MedDRA 22.1 System Organ Class Preferred Term Severity	Active UPA 15 mg QD (N=133) n (%)	Active UPA 30 mg QD (N=136) n (%)	Active UPA Total (N=269) n (%)
傷害、中毒および処置合併症 (Cont.)			
靭帯捻挫	0	1 (0.7)	1 (0.4)
Moderate	0	1 (0.7)	1 (0.4)
四肢損傷	1 (0.8)	0	1 (0.4)
Mild	1 (0.8)	0	1 (0.4)
皮膚擦過傷	0	1 (0.7)	1 (0.4)
Moderate	0	1 (0.7)	1 (0.4)
皮膚創傷	1 (0.8)	0	1 (0.4)
Moderate	1 (0.8)	0	1 (0.4)
臨床検査	14 (10.5)	10 (7.4)	24 (8.9)
Mild	11 (8.3)	5 (3.7)	16 (5.9)
Moderate	1 (0.8)	2 (1.5)	3 (1.1)
Severe	2 (1.5)	3 (2.2)	5 (1.9)
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)
Mild	2 (1.5)	1 (0.7)	3 (1.1)

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.
Table depicts the most severe adverse event for each preferred term as assessed for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

MedDRA 22.1 System Organ Class Preferred Term Severity	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 (Cont.)			
Moderate	1 (0.8)	1 (0.7)	2 (0.7)
Severe	0	1 (0.7)	1 (0.4)
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)
Mild	2 (1.5)	1 (0.7)	3 (1.1)
Moderate	0	1 (0.7)	1 (0.4)
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)
Mild	2 (1.5)	1 (0.7)	3 (1.1)
Severe	0	3 (2.2)	3 (1.1)
血中トリグリセリド増加	2 (1.5)	0	2 (0.7)
Mild	2 (1.5)	0	2 (0.7)
ヘモグロビン減少	1 (0.8)	1 (0.7)	2 (0.7)
Mild	1 (0.8)	1 (0.7)	2 (0.7)
肝酵素上昇	1 (0.8)	0	1 (0.4)
Severe	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.
Table depicts the most severe adverse event for each preferred term as assessed for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

MedDRA 22.1 System Organ Class Preferred Term Severity	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 (Cont.)			
リンパ球形態異常	0	1 (0.7)	1 (0.4)
Mild	0	1 (0.7)	1 (0.4)
骨髄球存在	0	1 (0.7)	1 (0.4)
Mild	0	1 (0.7)	1 (0.4)
好中球数減少	1 (0.8)	2 (1.5)	3 (1.1)
Mild	0	1 (0.7)	1 (0.4)
Moderate	0	1 (0.7)	1 (0.4)
Severe	1 (0.8)	0	1 (0.4)
尿中蛋白陽性	1 (0.8)	0	1 (0.4)
Mild	1 (0.8)	0	1 (0.4)
赤血球数減少	1 (0.8)	0	1 (0.4)
Mild	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)
Mild	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.
Table depicts the most severe adverse event for each preferred term as assessed for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

MedDRA 22.1 System Organ Class Preferred Term Severity	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 (Cont.)			
体重減少	1 (0.8)	0	1 (0.4)
Mild	1 (0.8)	0	1 (0.4)
白血球数減少	0	2 (1.5)	2 (0.7)
Mild	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)
Mild	4 (3.0)	3 (2.2)	7 (2.6)
Moderate	1 (0.8)	5 (3.7)	6 (2.2)
関節痛	0	6 (4.4)	6 (2.2)
Mild	0	2 (1.5)	2 (0.7)
Moderate	0	4 (2.9)	4 (1.5)
背部痛	1 (0.8)	1 (0.7)	2 (0.7)
Mild	1 (0.8)	0	1 (0.4)
Moderate	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.
Table depicts the most severe adverse event for each preferred term as assessed for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

MedDRA 22.1 System Organ Class Preferred Term Severity	Active UPA 15 mg QD (N=133) n (%)	Active UPA 30 mg QD (N=136) n (%)	Active UPA Total (N=269) n (%)
筋骨格系および結合組織障害 (Cont.)			
椎間板突出	1 (0.8)	0	1 (0.4)
Moderate	1 (0.8)	0	1 (0.4)
関節腫脹	0	1 (0.7)	1 (0.4)
Mild	0	1 (0.7)	1 (0.4)
筋肉痛	1 (0.8)	2 (1.5)	3 (1.1)
Mild	1 (0.8)	1 (0.7)	2 (0.7)
Moderate	0	1 (0.7)	1 (0.4)
四肢痛	1 (0.8)	0	1 (0.4)
Mild	1 (0.8)	0	1 (0.4)
滑液嚢腫	1 (0.8)	0	1 (0.4)
Mild	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)
Mild	4 (3.0)	0	4 (1.5)
Moderate	2 (1.5)	1 (0.7)	3 (1.1)

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.
Table depicts the most severe adverse event for each preferred term as assessed for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

MedDRA 22.1 System Organ Class Preferred Term Severity	UPA 15 mg QD (N=133) n (%)	Active UPA 30 mg QD (N=136) n (%)	UPA Total (N=269) 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.)			
平滑筋腫	1 (0.8)	0	1 (0.4)
Mild	1 (0.8)	0	1 (0.4)
皮膚乳頭腫	5 (3.8)	1 (0.7)	6 (2.2)
Mild	3 (2.3)	0	3 (1.1)
Moderate	2 (1.5)	1 (0.7)	3 (1.1)
神経系障害	4 (3.0)	7 (5.1)	11 (4.1)
Mild	2 (1.5)	6 (4.4)	8 (3.0)
Moderate	1 (0.8)	1 (0.7)	2 (0.7)
Severe	1 (0.8)	0	1 (0.4)
小脳出血	1 (0.8)	0	1 (0.4)
Severe	1 (0.8)	0	1 (0.4)
浮動性めまい	0	1 (0.7)	1 (0.4)
Mild	0	1 (0.7)	1 (0.4)
頭痛	2 (1.5)	3 (2.2)	5 (1.9)
Mild	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.
Table depicts the most severe adverse event for each preferred term as assessed for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

MedDRA 22.1 System Organ Class Preferred Term Severity	Active UPA 15 mg QD (N=133) n (%)	Active UPA 30 mg QD (N=136) n (%)	Active UPA Total (N=269) n (%)
神経系障害 (Cont.)			
Moderate	1 (0.8)	0	1 (0.4)
感覚鈍麻	1 (0.8)	0	1 (0.4)
Mild	1 (0.8)	0	1 (0.4)
ヘルペス後神経痛	0	1 (0.7)	1 (0.4)
Moderate	0	1 (0.7)	1 (0.4)
傾眠	0	3 (2.2)	3 (1.1)
Mild	0	3 (2.2)	3 (1.1)
精神障害	4 (3.0)	1 (0.7)	5 (1.9)
Mild	2 (1.5)	0	2 (0.7)
Moderate	2 (1.5)	1 (0.7)	3 (1.1)
抑うつ気分	1 (0.8)	0	1 (0.4)
Moderate	1 (0.8)	0	1 (0.4)
うつ病	1 (0.8)	0	1 (0.4)
Mild	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.
Table depicts the most severe adverse event for each preferred term as assessed for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

MedDRA 22.1 System Organ Class Preferred Term Severity	Active UPA 15 mg QD (N=133) n (%)	Active UPA 30 mg QD (N=136) n (%)	Active UPA Total (N=269) n (%)
精神障害 (Cont.)			
不眠症	1 (0.8)	0	1 (0.4)
Mild	1 (0.8)	0	1 (0.4)
落ち着きのなさ	0	1 (0.7)	1 (0.4)
Moderate	0	1 (0.7)	1 (0.4)
身体症状症	1 (0.8)	0	1 (0.4)
Moderate	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)
Mild	4 (3.0)	3 (2.2)	7 (2.6)
Moderate	4 (3.0)	5 (3.7)	9 (3.3)
喘息	2 (1.5)	3 (2.2)	5 (1.9)
Mild	1 (0.8)	0	1 (0.4)
Moderate	1 (0.8)	3 (2.2)	4 (1.5)
慢性気管支炎	0	1 (0.7)	1 (0.4)
Mild	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.
Table depicts the most severe adverse event for each preferred term as assessed for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

MedDRA 22.1 System Organ Class Preferred Term Severity	Active UPA 15 mg QD (N=133) n (%)	Active UPA 30 mg QD (N=136) n (%)	Active UPA Total (N=269) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)			
咳嗽	1 (0.8)	1 (0.7)	2 (0.7)
Mild	0	1 (0.7)	1 (0.4)
Moderate	1 (0.8)	0	1 (0.4)
鼻出血	0	1 (0.7)	1 (0.4)
Moderate	0	1 (0.7)	1 (0.4)
口腔咽頭痛	4 (3.0)	3 (2.2)	7 (2.6)
Mild	3 (2.3)	2 (1.5)	5 (1.9)
Moderate	1 (0.8)	1 (0.7)	2 (0.7)
上気道の炎症	1 (0.8)	0	1 (0.4)
Moderate	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)
Mild	12 (9.0)	24 (17.6)	36 (13.4)
Moderate	17 (12.8)	21 (15.4)	38 (14.1)

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.
Table depicts the most severe adverse event for each preferred term as assessed for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

MedDRA 22.1 System Organ Class Preferred Term Severity	Active UPA 15 mg QD (N=133) n (%)	Active UPA 30 mg QD (N=136) n (%)	Active UPA Total (N=269) n (%)
皮膚および皮下組織障害 (Cont.)			
ざ瘡	20 (15.0)	38 (27.9)	58 (21.6)
Mild	10 (7.5)	22 (16.2)	32 (11.9)
Moderate	10 (7.5)	16 (11.8)	26 (9.7)
脱毛症	1 (0.8)	0	1 (0.4)
Moderate	1 (0.8)	0	1 (0.4)
水疱	1 (0.8)	1 (0.7)	2 (0.7)
Mild	1 (0.8)	0	1 (0.4)
Moderate	0	1 (0.7)	1 (0.4)
アトピー性皮膚炎	5 (3.8)	1 (0.7)	6 (2.2)
Mild	1 (0.8)	0	1 (0.4)
Moderate	4 (3.0)	1 (0.7)	5 (1.9)
接触皮膚炎	1 (0.8)	1 (0.7)	2 (0.7)
Mild	1 (0.8)	1 (0.7)	2 (0.7)
紅斑	1 (0.8)	0	1 (0.4)
Moderate	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.
Table depicts the most severe adverse event for each preferred term as assessed for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

MedDRA 22.1 System Organ Class Preferred Term Severity	Active UPA 15 mg QD (N=133) n (%)	Active UPA 30 mg QD (N=136) n (%)	Active UPA Total (N=269) n (%)
皮膚および皮下組織障害 (Cont.)			
過角化	1 (0.8)	0	1 (0.4)
Moderate	1 (0.8)	0	1 (0.4)
汗疹	1 (0.8)	2 (1.5)	3 (1.1)
Moderate	1 (0.8)	2 (1.5)	3 (1.1)
口囲皮膚炎	1 (0.8)	0	1 (0.4)
Moderate	1 (0.8)	0	1 (0.4)
小水疱性皮疹	0	1 (0.7)	1 (0.4)
Mild	0	1 (0.7)	1 (0.4)
脂漏性皮膚炎	1 (0.8)	0	1 (0.4)
Mild	1 (0.8)	0	1 (0.4)
皮膚亀裂	0	1 (0.7)	1 (0.4)
Mild	0	1 (0.7)	1 (0.4)
日光皮膚炎	2 (1.5)	0	2 (0.7)
Mild	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.
Table depicts the most severe adverse event for each preferred term as assessed for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

MedDRA 22.1 System Organ Class Preferred Term Severity	Active UPA 15 mg QD (N=133) n (%)	Active UPA 30 mg QD (N=136) n (%)	Active UPA Total (N=269) n (%)
皮膚および皮下組織障害 (Cont.)			
Moderate	1 (0.8)	0	1 (0.4)
蕁麻疹	1 (0.8)	2 (1.5)	3 (1.1)
Mild	1 (0.8)	1 (0.7)	2 (0.7)
Moderate	0	1 (0.7)	1 (0.4)
接触蕁麻疹	0	1 (0.7)	1 (0.4)
Mild	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.
Table depicts the most severe adverse event for each preferred term as assessed for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

相互参照：M17-377 試験 CSR W24 Table 14.3　1.10.2

表 2.7.4.7-32. 投与 24 週時データカットオフまでの 100 人年あたりの有害事象の器官別大分類別，基本語別及び最大重症度別の集計結果（ALL_UPA 集団）：M17-377 試験

MedDRA 22.1 System Organ Class Preferred Term Severity	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)
Any adverse event	208 (251.3)	245 (300.7)	453 (275.8)
Mild	102 (123.2)	129 (158.3)	231 (140.7)
Moderate	100 (120.8)	107 (131.3)	207 (126.0)
Severe	6 (7.2)	9 (11.0)	15 (9.1)
血液およびリンパ系障害	1 (1.2)	8 (9.8)	9 (5.5)
Mild	1 (1.2)	5 (6.1)	6 (3.7)
Moderate	0	2 (2.5)	2 (1.2)
Severe	0	1 (1.2)	1 (0.6)
貧血	0	4 (4.9)	4 (2.4)
Mild	0	4 (4.9)	4 (2.4)
リンパ節症	1 (1.2)	0	1 (0.6)
Mild	1 (1.2)	0	1 (0.6)
好中球減少症	0	4 (4.9)	4 (2.4)
Mild	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.
Subjects are counted once in each row, regardless of the number of events they may have had.
E/100PY = Events per 100 patient-years.

MedDRA 22.1 System Organ Class Preferred Term Severity	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)
Moderate	0	2 (2.5)	2 (1.2)
Severe	0	1 (1.2)	1 (0.6)
心臓障害	1 (1.2)	0	1 (0.6)
Moderate	1 (1.2)	0	1 (0.6)
動悸	1 (1.2)	0	1 (0.6)
Moderate	1 (1.2)	0	1 (0.6)
耳および迷路障害	1 (1.2)	1 (1.2)	2 (1.2)
Mild	1 (1.2)	1 (1.2)	2 (1.2)
耳鳴	1 (1.2)	0	1 (0.6)
Mild	1 (1.2)	0	1 (0.6)
頭位性回転性めまい	0	1 (1.2)	1 (0.6)
Mild	0	1 (1.2)	1 (0.6)
眼障害	5 (6.0)	3 (3.7)	8 (4.9)

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

MedDRA 22.1 System Organ Class Preferred Term Severity	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)
Mild	1 (1.2)	2 (2.5)	3 (1.8)
Moderate	4 (4.8)	1 (1.2)	5 (3.0)
アトピー性白内障	1 (1.2)	0	1 (0.6)
Mild	1 (1.2)	0	1 (0.6)
結膜充血	1 (1.2)	0	1 (0.6)
Moderate	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)
Moderate	3 (3.6)	1 (1.2)	4 (2.4)
ドライアイ	0	1 (1.2)	1 (0.6)
Mild	0	1 (1.2)	1 (0.6)
夜盲	0	1 (1.2)	1 (0.6)
Mild	0	1 (1.2)	1 (0.6)
胃腸障害	7 (8.5)	14 (17.2)	21 (12.8)

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

MedDRA 22.1 System Organ Class Preferred Term Severity	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)
Mild	4 (4.8)	9 (11.0)	13 (7.9)
Moderate	3 (3.6)	5 (6.1)	8 (4.9)
腹部不快感	0	3 (3.7)	3 (1.8)
Mild	0	2 (2.5)	2 (1.2)
Moderate	0	1 (1.2)	1 (0.6)
腹部膨満	0	1 (1.2)	1 (0.6)
Mild	0	1 (1.2)	1 (0.6)
上腹部痛	2 (2.4)	0	2 (1.2)
Mild	1 (1.2)	0	1 (0.6)
Moderate	1 (1.2)	0	1 (0.6)
慢性胃炎	0	1 (1.2)	1 (0.6)
Mild	0	1 (1.2)	1 (0.6)
便秘	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.
Subjects are counted once in each row, regardless of the number of events they may have had.
E/100PY = Events per 100 patient-years.

MedDRA 22.1 System Organ Class Preferred Term Severity	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)
Mild	0	1 (1.2)	1 (0.6)
齲歯	1 (1.2)	0	1 (0.6)
Moderate	1 (1.2)	0	1 (0.6)
下痢	1 (1.2)	4 (4.9)	5 (3.0)
Mild	1 (1.2)	2 (2.5)	3 (1.8)
Moderate	0	2 (2.5)	2 (1.2)
食中毒	1 (1.2)	0	1 (0.6)
Moderate	1 (1.2)	0	1 (0.6)
血便排泄	1 (1.2)	0	1 (0.6)
Mild	1 (1.2)	0	1 (0.6)
胃酸過多	0	1 (1.2)	1 (0.6)
Moderate	0	1 (1.2)	1 (0.6)
粘液便	1 (1.2)	0	1 (0.6)

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

MedDRA 22.1 System Organ Class Preferred Term Severity	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)
Mild	1 (1.2)	0	1 (0.6)
口内炎	0	3 (3.7)	3 (1.8)
Mild	0	2 (2.5)	2 (1.2)
Moderate	0	1 (1.2)	1 (0.6)
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)
Mild	8 (9.7)	10 (12.3)	18 (11.0)
Moderate	2 (2.4)	0	2 (1.2)
胸痛	0	1 (1.2)	1 (0.6)
Mild	0	1 (1.2)	1 (0.6)
疲労	1 (1.2)	0	1 (0.6)
Mild	1 (1.2)	0	1 (0.6)
倦怠感	1 (1.2)	2 (2.5)	3 (1.8)
Mild	1 (1.2)	2 (2.5)	3 (1.8)

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MedDRA 22.1 System Organ Class Preferred Term Severity	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)
末梢性浮腫	1 (1.2)	1 (1.2)	2 (1.2)
Mild	1 (1.2)	1 (1.2)	2 (1.2)
発熱	7 (8.5)	6 (7.4)	13 (7.9)
Mild	5 (6.0)	6 (7.4)	11 (6.7)
Moderate	2 (2.4)	0	2 (1.2)
感染症および寄生虫症	89 (107.5)	104 (127.7)	193 (117.5)
Mild	31 (37.5)	46 (56.5)	77 (46.9)
Moderate	55 (66.5)	54 (66.3)	109 (66.4)
Severe	3 (3.6)	4 (4.9)	7 (4.3)
気管支炎	0	3 (3.7)	3 (1.8)
Mild	0	2 (2.5)	2 (1.2)
Moderate	0	1 (1.2)	1 (0.6)
よう	0	1 (1.2)	1 (0.6)

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MedDRA 22.1 System Organ Class Preferred Term Severity	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)
Moderate	0	1 (1.2)	1 (0.6)
蜂巣炎	2 (2.4)	0	2 (1.2)
Mild	1 (1.2)	0	1 (0.6)
Severe	1 (1.2)	0	1 (0.6)
結膜炎	2 (2.4)	3 (3.7)	5 (3.0)
Mild	1 (1.2)	1 (1.2)	2 (1.2)
Moderate	1 (1.2)	2 (2.5)	3 (1.8)
膀胱炎	1 (1.2)	1 (1.2)	2 (1.2)
Mild	0	1 (1.2)	1 (0.6)
Moderate	1 (1.2)	0	1 (0.6)
爪の皮膚糸状菌症	0	1 (1.2)	1 (0.6)
Mild	0	1 (1.2)	1 (0.6)
感染性腸炎	0	1 (1.2)	1 (0.6)

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Moderate	0	1 (1.2)	1 (0.6)
丹毒	1 (1.2)	0	1 (0.6)
Moderate	1 (1.2)	0	1 (0.6)
毛包炎	6 (7.2)	4 (4.9)	10 (6.1)
Mild	1 (1.2)	1 (1.2)	2 (1.2)
Moderate	5 (6.0)	3 (3.7)	8 (4.9)
せつ	5 (6.0)	2 (2.5)	7 (4.3)
Mild	2 (2.4)	1 (1.2)	3 (1.8)
Moderate	3 (3.6)	1 (1.2)	4 (2.4)
胃腸炎	0	1 (1.2)	1 (0.6)
Mild	0	1 (1.2)	1 (0.6)
ウイルス性胃腸炎	0	1 (1.2)	1 (0.6)
Mild	0	1 (1.2)	1 (0.6)

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陰部ヘルペス	1 (1.2)	0	1 (0.6)
Moderate	1 (1.2)	0	1 (0.6)
歯肉炎	1 (1.2)	1 (1.2)	2 (1.2)
Mild	0	1 (1.2)	1 (0.6)
Moderate	1 (1.2)	0	1 (0.6)
手足口病	0	1 (1.2)	1 (0.6)
Moderate	0	1 (1.2)	1 (0.6)
単純ヘルペス	7 (8.5)	5 (6.1)	12 (7.3)
Mild	4 (4.8)	3 (3.7)	7 (4.3)
Moderate	3 (3.6)	1 (1.2)	4 (2.4)
Severe	0	1 (1.2)	1 (0.6)
ヘルペスウイルス感染	1 (1.2)	0	1 (0.6)
Moderate	1 (1.2)	0	1 (0.6)

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MedDRA 22.1 System Organ Class Preferred Term Severity	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)
帯状疱疹	5 (6.0)	11 (13.5)	16 (9.7)
Mild	1 (1.2)	0	1 (0.6)
Moderate	3 (3.6)	9 (11.0)	12 (7.3)
Severe	1 (1.2)	2 (2.5)	3 (1.8)
播種性帯状疱疹	1 (1.2)	0	1 (0.6)
Moderate	1 (1.2)	0	1 (0.6)
麦粒腫	1 (1.2)	2 (2.5)	3 (1.8)
Mild	0	1 (1.2)	1 (0.6)
Moderate	1 (1.2)	1 (1.2)	2 (1.2)
膿痂疹	1 (1.2)	0	1 (0.6)
Moderate	1 (1.2)	0	1 (0.6)
感染	1 (1.2)	1 (1.2)	2 (1.2)
Moderate	1 (1.2)	1 (1.2)	2 (1.2)

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インフルエンザ	1 (1.2)	3 (3.7)	4 (2.4)
Moderate	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)
Moderate	4 (4.8)	2 (2.5)	6 (3.7)
伝染性軟属腫	0	1 (1.2)	1 (0.6)
Mild	0	1 (1.2)	1 (0.6)
上咽頭炎	30 (36.2)	38 (46.6)	68 (41.4)
Mild	16 (19.3)	24 (29.5)	40 (24.4)
Moderate	14 (16.9)	14 (17.2)	28 (17.0)
口腔ヘルペス	3 (3.6)	6 (7.4)	9 (5.5)
Mild	0	4 (4.9)	4 (2.4)
Moderate	3 (3.6)	2 (2.5)	5 (3.0)
外耳炎	0	2 (2.5)	2 (1.2)

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Moderate	0	2 (2.5)	2 (1.2)
中耳炎	0	1 (1.2)	1 (0.6)
Severe	0	1 (1.2)	1 (0.6)
爪囲炎	0	1 (1.2)	1 (0.6)
Mild	0	1 (1.2)	1 (0.6)
咽頭炎	1 (1.2)	1 (1.2)	2 (1.2)
Mild	1 (1.2)	0	1 (0.6)
Moderate	0	1 (1.2)	1 (0.6)
細菌性咽頭炎	0	1 (1.2)	1 (0.6)
Moderate	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)
Severe	1 (1.2)	0	1 (0.6)
副鼻腔炎	0	1 (1.2)	1 (0.6)

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Mild	0	1 (1.2)	1 (0.6)
皮膚感染	1 (1.2)	0	1 (0.6)
Moderate	1 (1.2)	0	1 (0.6)
皮下組織膿瘍	1 (1.2)	0	1 (0.6)
Moderate	1 (1.2)	0	1 (0.6)
股部白癬	0	1 (1.2)	1 (0.6)
Moderate	0	1 (1.2)	1 (0.6)
足部白癬	0	3 (3.7)	3 (1.8)
Mild	0	1 (1.2)	1 (0.6)
Moderate	0	2 (2.5)	2 (1.2)
癪風	1 (1.2)	0	1 (0.6)
Mild	1 (1.2)	0	1 (0.6)
扁桃炎	6 (7.2)	2 (2.5)	8 (4.9)

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Mild	1 (1.2)	0	1 (0.6)
Moderate	5 (6.0)	2 (2.5)	7 (4.3)
上気道感染	3 (3.6)	1 (1.2)	4 (2.4)
Mild	1 (1.2)	0	1 (0.6)
Moderate	2 (2.4)	1 (1.2)	3 (1.8)
尿路感染	1 (1.2)	0	1 (0.6)
Mild	1 (1.2)	0	1 (0.6)
ウイルス性上気道感染	0	1 (1.2)	1 (0.6)
Moderate	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)
Mild	2 (2.4)	4 (4.9)	6 (3.7)
Moderate	4 (4.8)	4 (4.9)	8 (4.9)
節足動物咬傷	0	3 (3.7)	3 (1.8)

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Mild	0	3 (3.7)	3 (1.8)
節足動物刺傷	1 (1.2)	0	1 (0.6)
Mild	1 (1.2)	0	1 (0.6)
剥離骨折	1 (1.2)	0	1 (0.6)
Moderate	1 (1.2)	0	1 (0.6)
骨挫傷	0	1 (1.2)	1 (0.6)
Mild	0	1 (1.2)	1 (0.6)
大腿骨骨折	0	1 (1.2)	1 (0.6)
Moderate	0	1 (1.2)	1 (0.6)
足骨折	1 (1.2)	0	1 (0.6)
Moderate	1 (1.2)	0	1 (0.6)
手骨折	1 (1.2)	0	1 (0.6)
Moderate	1 (1.2)	0	1 (0.6)

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熱射病	0	1 (1.2)	1 (0.6)
Moderate	0	1 (1.2)	1 (0.6)
靭帯捻挫	0	1 (1.2)	1 (0.6)
Moderate	0	1 (1.2)	1 (0.6)
四肢損傷	1 (1.2)	0	1 (0.6)
Mild	1 (1.2)	0	1 (0.6)
皮膚擦過傷	0	1 (1.2)	1 (0.6)
Moderate	0	1 (1.2)	1 (0.6)
皮膚創傷	1 (1.2)	0	1 (0.6)
Moderate	1 (1.2)	0	1 (0.6)
臨床検査	18 (21.7)	17 (20.9)	35 (21.3)
Mild	15 (18.1)	9 (11.0)	24 (14.6)
Moderate	1 (1.2)	4 (4.9)	5 (3.0)

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Severe	2 (2.4)	4 (4.9)	6 (3.7)
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)
Mild	3 (3.6)	1 (1.2)	4 (2.4)
Moderate	1 (1.2)	2 (2.5)	3 (1.8)
Severe	0	1 (1.2)	1 (0.6)
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)
Mild	2 (2.4)	1 (1.2)	3 (1.8)
Moderate	0	1 (1.2)	1 (0.6)
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)
Mild	2 (2.4)	1 (1.2)	3 (1.8)
Severe	0	3 (3.7)	3 (1.8)
血中トリグリセリド増加	2 (2.4)	0	2 (1.2)
Mild	2 (2.4)	0	2 (1.2)

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ヘモグロビン減少	2 (2.4)	1 (1.2)	3 (1.8)
Mild	2 (2.4)	1 (1.2)	3 (1.8)
肝酵素上昇	1 (1.2)	0	1 (0.6)
Severe	1 (1.2)	0	1 (0.6)
リンパ球形態異常	0	1 (1.2)	1 (0.6)
Mild	0	1 (1.2)	1 (0.6)
骨髄球存在	0	1 (1.2)	1 (0.6)
Mild	0	1 (1.2)	1 (0.6)
好中球数減少	1 (1.2)	2 (2.5)	3 (1.8)
Mild	0	1 (1.2)	1 (0.6)
Moderate	0	1 (1.2)	1 (0.6)
Severe	1 (1.2)	0	1 (0.6)
尿中蛋白陽性	1 (1.2)	0	1 (0.6)

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Mild	1 (1.2)	0	1 (0.6)
赤血球数減少	1 (1.2)	0	1 (0.6)
Mild	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)
Mild	1 (1.2)	0	1 (0.6)
体重減少	1 (1.2)	0	1 (0.6)
Mild	1 (1.2)	0	1 (0.6)
白血球数減少	0	2 (2.5)	2 (1.2)
Mild	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)
Mild	4 (4.8)	4 (4.9)	8 (4.9)
Moderate	1 (1.2)	8 (9.8)	9 (5.5)
関節痛	0	8 (9.8)	8 (4.9)

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Subjects are counted once in each row, regardless of the number of events they may have had.
E/100PY = Events per 100 patient-years.

MedDRA 22.1 System Organ Class Preferred Term Severity	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)
Mild	0	2 (2.5)	2 (1.2)
Moderate	0	6 (7.4)	6 (3.7)
背部痛	1 (1.2)	1 (1.2)	2 (1.2)
Mild	1 (1.2)	0	1 (0.6)
Moderate	0	1 (1.2)	1 (0.6)
椎間板突出	1 (1.2)	0	1 (0.6)
Moderate	1 (1.2)	0	1 (0.6)
関節腫脹	0	1 (1.2)	1 (0.6)
Mild	0	1 (1.2)	1 (0.6)
筋肉痛	1 (1.2)	2 (2.5)	3 (1.8)
Mild	1 (1.2)	1 (1.2)	2 (1.2)
Moderate	0	1 (1.2)	1 (0.6)
四肢痛	1 (1.2)	0	1 (0.6)

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Subjects are counted once in each row, regardless of the number of events they may have had.
E/100PY = Events per 100 patient-years.

MedDRA 22.1 System Organ Class Preferred Term Severity	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)
Mild	1 (1.2)	0	1 (0.6)
滑液嚢腫	1 (1.2)	0	1 (0.6)
Mild	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)
Mild	4 (4.8)	0	4 (2.4)
Moderate	2 (2.4)	1 (1.2)	3 (1.8)
平滑筋腫	1 (1.2)	0	1 (0.6)
Mild	1 (1.2)	0	1 (0.6)
皮膚乳頭腫	5 (6.0)	1 (1.2)	6 (3.7)
Mild	3 (3.6)	0	3 (1.8)
Moderate	2 (2.4)	1 (1.2)	3 (1.8)
神経系障害	6 (7.2)	8 (9.8)	14 (8.5)
Mild	4 (4.8)	7 (8.6)	11 (6.7)

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

MedDRA 22.1 System Organ Class Preferred Term Severity	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)
Moderate	1 (1.2)	1 (1.2)	2 (1.2)
Severe	1 (1.2)	0	1 (0.6)
小脳出血	1 (1.2)	0	1 (0.6)
Severe	1 (1.2)	0	1 (0.6)
浮動性めまい	0	1 (1.2)	1 (0.6)
Mild	0	1 (1.2)	1 (0.6)
頭痛	4 (4.8)	3 (3.7)	7 (4.3)
Mild	3 (3.6)	3 (3.7)	6 (3.7)
Moderate	1 (1.2)	0	1 (0.6)
感覚鈍麻	1 (1.2)	0	1 (0.6)
Mild	1 (1.2)	0	1 (0.6)
ヘルペス後神経痛	0	1 (1.2)	1 (0.6)
Moderate	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.
Subjects are counted once in each row, regardless of the number of events they may have had.
E/100PY = Events per 100 patient-years.

MedDRA 22.1 System Organ Class Preferred Term Severity	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)
傾眠	0	3 (3.7)	3 (1.8)
Mild	0	3 (3.7)	3 (1.8)
精神障害	4 (4.8)	1 (1.2)	5 (3.0)
Mild	2 (2.4)	0	2 (1.2)
Moderate	2 (2.4)	1 (1.2)	3 (1.8)
抑うつ気分	1 (1.2)	0	1 (0.6)
Moderate	1 (1.2)	0	1 (0.6)
うつ病	1 (1.2)	0	1 (0.6)
Mild	1 (1.2)	0	1 (0.6)
不眠症	1 (1.2)	0	1 (0.6)
Mild	1 (1.2)	0	1 (0.6)
落ち着きのなさ	0	1 (1.2)	1 (0.6)
Moderate	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.
E/100PY = Events per 100 patient-years.

MedDRA 22.1 System Organ Class Preferred Term Severity	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)
身体症状症	1 (1.2)	0	1 (0.6)
Moderate	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)
Mild	4 (4.8)	4 (4.9)	8 (4.9)
Moderate	4 (4.8)	5 (6.1)	9 (5.5)
喘息	2 (2.4)	3 (3.7)	5 (3.0)
Mild	1 (1.2)	0	1 (0.6)
Moderate	1 (1.2)	3 (3.7)	4 (2.4)
慢性気管支炎	0	1 (1.2)	1 (0.6)
Mild	0	1 (1.2)	1 (0.6)
咳嗽	1 (1.2)	1 (1.2)	2 (1.2)
Mild	0	1 (1.2)	1 (0.6)
Moderate	1 (1.2)	0	1 (0.6)

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Subjects are counted once in each row, regardless of the number of events they may have had.
E/100PY = Events per 100 patient-years.

MedDRA 22.1 System Organ Class Preferred Term Severity	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)
鼻出血	0	1 (1.2)	1 (0.6)
Moderate	0	1 (1.2)	1 (0.6)
口腔咽頭痛	4 (4.8)	3 (3.7)	7 (4.3)
Mild	3 (3.6)	2 (2.5)	5 (3.0)
Moderate	1 (1.2)	1 (1.2)	2 (1.2)
上気道の炎症	1 (1.2)	0	1 (0.6)
Moderate	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)
Mild	21 (25.4)	28 (34.4)	49 (29.8)
Moderate	20 (24.2)	21 (25.8)	41 (25.0)
ざ瘡	24 (29.0)	39 (47.9)	63 (38.4)
Mild	14 (16.9)	23 (28.2)	37 (22.5)
Moderate	10 (12.1)	16 (19.6)	26 (15.8)

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Subjects are counted once in each row, regardless of the number of events they may have had.
E/100PY = Events per 100 patient-years.

MedDRA 22.1 System Organ Class Preferred Term Severity	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)
脱毛症	1 (1.2)	0	1 (0.6)
Moderate	1 (1.2)	0	1 (0.6)
水疱	1 (1.2)	1 (1.2)	2 (1.2)
Mild	1 (1.2)	0	1 (0.6)
Moderate	0	1 (1.2)	1 (0.6)
アトピー性皮膚炎	5 (6.0)	1 (1.2)	6 (3.7)
Mild	1 (1.2)	0	1 (0.6)
Moderate	4 (4.8)	1 (1.2)	5 (3.0)
接触皮膚炎	1 (1.2)	1 (1.2)	2 (1.2)
Mild	1 (1.2)	1 (1.2)	2 (1.2)
紅斑	1 (1.2)	0	1 (0.6)
Moderate	1 (1.2)	0	1 (0.6)
過角化	1 (1.2)	0	1 (0.6)

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Subjects are counted once in each row, regardless of the number of events they may have had.
E/100PY = Events per 100 patient-years.

MedDRA 22.1 System Organ Class Preferred Term Severity	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)
Moderate	1 (1.2)	0	1 (0.6)
汗疹	1 (1.2)	2 (2.5)	3 (1.8)
Moderate	1 (1.2)	2 (2.5)	3 (1.8)
口囲皮膚炎	1 (1.2)	0	1 (0.6)
Moderate	1 (1.2)	0	1 (0.6)
小水疱性皮疹	0	1 (1.2)	1 (0.6)
Mild	0	1 (1.2)	1 (0.6)
脂漏性皮膚炎	1 (1.2)	0	1 (0.6)
Mild	1 (1.2)	0	1 (0.6)
皮膚亀裂	0	1 (1.2)	1 (0.6)
Mild	0	1 (1.2)	1 (0.6)
日光皮膚炎	2 (2.4)	0	2 (1.2)
Mild	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.
Subjects are counted once in each row, regardless of the number of events they may have had.
E/100PY = Events per 100 patient-years.

MedDRA 22.1 System Organ Class Preferred Term Severity	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)
Moderate	1 (1.2)	0	1 (0.6)
蕁麻疹	2 (2.4)	2 (2.5)	4 (2.4)
Mild	2 (2.4)	1 (1.2)	3 (1.8)
Moderate	0	1 (1.2)	1 (0.6)
接触蕁麻疹	0	1 (1.2)	1 (0.6)
Mild	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.
Subjects are counted once in each row, regardless of the number of events they may have had.
E/100PY = Events per 100 patient-years.

相互参照：M17-377 試験 CSR W24 Table 14.3　1.10.3

表 2.7.4.7-33. 第 1 ピリオド（投与 16 週時まで）の有害事象の器官別大分類別，基本語別及び最大重症度別の集計結果（Safety 1 集団）：M16-048 試験

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	PLACEBO (N=40) n (%)	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=42) n (%)	UPA TOTAL (N=126) n (%)
ANY ADVERSE EVENT	25 (62.5)	31 (73.8)	32 (76.2)	33 (78.6)	96 (76.2)
MILD	17	17	19	17	53
MODERATE	7	14	12	16	42
SEVERE	1	0	1	0	1
血液およびリンパ系障害					
貧血	0	0	0	1 (2.4)	1 (0.8)
MODERATE	0	0	0	1	1
内出血発生の増加傾向	0	0	0	1 (2.4)	1 (0.8)
MILD	0	0	0	1	1
リンパ節炎	0	0	0	1 (2.4)	1 (0.8)
MILD	0	0	0	1	1
リンパ節症	0	1 (2.4)	0	0	1 (0.8)
MILD	0	1	0	0	1
リンパ球減少症	0	0	1 (2.4)	0	1 (0.8)
MILD	0	0	1	0	1
好中球減少症	0	1 (2.4)	2 (4.8)	2 (4.8)	5 (4.0)
MILD	0	0	2	2	4
MODERATE	0	1	0	0	1
SUBJECTS WITH ONE OR MORE EVENTS	0	2 (4.8)	2 (4.8)	5 (11.9)	9 (7.1)
MILD	0	1	2	4	7
MODERATE	0	1	0	1	2
心臓障害					

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	PLACEBO (N=40) n (%)	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=42) n (%)	TOTAL (N=126) n (%)
心房細動	1 (2.5)	0	0	0	0
SEVERE	1	0	0	0	0
動悸	0	0	1 (2.4)	0	1 (0.8)
MILD	0	0	1	0	1
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.5)	0	1 (2.4)	0	1 (0.8)
MILD	0	0	1	0	1
SEVERE	1	0	0	0	0
内分泌障害					
甲状腺腫	0	1 (2.4)	0	0	1 (0.8)
MILD	0	1	0	0	1
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (2.4)	0	0	1 (0.8)
MILD	0	1	0	0	1
眼障害					
白内障	0	0	0	1 (2.4)	1 (0.8)
MODERATE	0	0	0	1	1
霰粒腫	0	1 (2.4)	0	0	1 (0.8)
MILD	0	1	0	0	1
ドライアイ	0	0	1 (2.4)	0	1 (0.8)
MILD	0	0	1	0	1
眼刺激	0	0	0	1 (2.4)	1 (0.8)
MILD	0	0	0	1	1
流涙増加	0	0	1 (2.4)	1 (2.4)	2 (1.6)
MILD	0	0	1	1	2
点状角膜炎	0	0	1 (2.4)	0	1 (0.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	PLACEBO (N=40) n (%)	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=42) n (%)	UPA TOTAL (N=126) n (%)
MODERATE	0	0	1	0	1
潰瘍性角膜炎	0	1 (2.4)	0	0	1 (0.8)
MODERATE	0	1	0	0	1
霧視	0	0	0	1 (2.4)	1 (0.8)
MILD	0	0	0	1	1
SUBJECTS WITH ONE OR MORE EVENTS	0	2 (4.8)	3 (7.1)	4 (9.5)	9 (7.1)
MILD	0	1	2	3	6
MODERATE	0	1	1	1	3
胃腸障害					
腹痛	1 (2.5)	0	2 (4.8)	1 (2.4)	3 (2.4)
MILD	1	0	2	1	3
上腹部痛	0	0	1 (2.4)	0	1 (0.8)
MILD	0	0	1	0	1
下痢	2 (5.0)	2 (4.8)	2 (4.8)	0	4 (3.2)
MILD	2	2	2	0	4
消化不良	0	0	0	1 (2.4)	1 (0.8)
MILD	0	0	0	1	1
胃炎	0	0	1 (2.4)	0	1 (0.8)
MILD	0	0	1	0	1
消化器痛	0	1 (2.4)	0	0	1 (0.8)
MILD	0	1	0	0	1
悪心	1 (2.5)	3 (7.1)	1 (2.4)	3 (7.1)	7 (5.6)
MILD	1	3	1	3	7
SUBJECTS WITH ONE OR MORE EVENTS	4 (10.0)	3 (7.1)	5 (11.9)	5 (11.9)	13 (10.3)
MILD	4	3	5	5	13

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	PLACEBO (N=40) n (%)	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=42) n (%)	TOTAL (N=126) n (%)
一般・全身障害および投与部位の状態					
嚢胞	0	0	0	1 (2.4)	1 (0.8)
MILD	0	0	0	1	1
顔面浮腫	0	0	0	1 (2.4)	1 (0.8)
MODERATE	0	0	0	1	1
疲労	0	1 (2.4)	2 (4.8)	2 (4.8)	5 (4.0)
MILD	0	1	2	1	4
MODERATE	0	0	0	1	1
インフルエンザ様疾患	1 (2.5)	0	1 (2.4)	0	1 (0.8)
MILD	0	0	1	0	1
MODERATE	1	0	0	0	0
非心臓性胸痛	0	0	0	1 (2.4)	1 (0.8)
MILD	0	0	0	1	1
浮腫	0	1 (2.4)	0	1 (2.4)	2 (1.6)
MILD	0	1	0	0	1
MODERATE	0	0	0	1	1
末梢性浮腫	1 (2.5)	0	0	1 (2.4)	1 (0.8)
MILD	1	0	0	1	1
疼痛	0	0	0	1 (2.4)	1 (0.8)
MILD	0	0	0	1	1
末梢腫脹	0	1 (2.4)	0	0	1 (0.8)
MILD	0	1	0	0	1
発熱	1 (2.5)	1 (2.4)	0	0	1 (0.8)
MILD	1	1	0	0	1
SUBJECTS WITH ONE OR MORE EVENTS	3 (7.5)	3 (7.1)	2 (4.8)	6 (14.3)	11 (8.7)
MILD	2	3	2	4	9
MODERATE	1	0	0	2	2

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	PLACEBO (N=40) n (%)	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=42) n (%)	UPA TOTAL (N=126) n (%)
肝胆道系障害					
脂肪肝	0	0	1 (2.4)	0	1 (0.8)
MILD	0	0	1	0	1
SUBJECTS WITH ONE OR MORE EVENTS	0	0	1 (2.4)	0	1 (0.8)
MILD	0	0	1	0	1
感染症および寄生虫症					
膿瘍	0	1 (2.4)	0	0	1 (0.8)
MILD	0	1	0	0	1
虫垂炎	0	0	1 (2.4)	0	1 (0.8)
SEVERE	0	0	1	0	1
ボトリオミセス症	0	0	0	1 (2.4)	1 (0.8)
MODERATE	0	0	0	1	1
蜂巣炎	1 (2.5)	0	0	0	0
MODERATE	1	0	0	0	0
結膜炎	0	2 (4.8)	0	0	2 (1.6)
MODERATE	0	2	0	0	2
眼感染	0	1 (2.4)	0	0	1 (0.8)
MODERATE	0	1	0	0	1
毛包炎	0	2 (4.8)	2 (4.8)	0	4 (3.2)
MILD	0	1	1	0	2
MODERATE	0	1	1	0	2
胃腸炎	1 (2.5)	1 (2.4)	1 (2.4)	1 (2.4)	3 (2.4)
MILD	0	1	1	1	3
MODERATE	1	0	0	0	0
単純ヘルペス	0	0	2 (4.8)	1 (2.4)	3 (2.4)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	PLACEBO (N=40) n (%)		UPA 7.5 MG QD (N=42) n (%)		UPA 15 MG QD (N=42) n (%)		UPA 30 MG QD (N=42) n (%)		UPA TOTAL (N=126) n (%)	
MILD	0		0		0		1		1	
MODERATE	0		0		2		0		2	
麦粒腫	1	(2.5)	0		0		0		0	
MILD	1		0		0		0		0	
膿痂疹	0		1	(2.4)	0		2	(4.8)	3	(2.4)
MILD	0		1		0		1		2	
MODERATE	0		0		0		1		1	
インフルエンザ	0		3	(7.1)	0		0		3	(2.4)
MILD	0		3		0		0		3	
下気道感染	0		0		1	(2.4)	0		1	(0.8)
MILD	0		0		1		0		1	
リンパ管炎	0		0		1	(2.4)	0		1	(0.8)
MODERATE	0		0		1		0		1	
上咽頭炎	1	(2.5)	2	(4.8)	4	(9.5)	3	(7.1)	9	(7.1)
MILD	1		2		2		3		7	
MODERATE	0		0		2		0		2	
口腔ヘルペス	0		0		1	(2.4)	0		1	(0.8)
MILD	0		0		1		0		1	
外耳炎	0		0		1	(2.4)	0		1	(0.8)
MODERATE	0		0		1		0		1	
爪囲炎	0		0		1	(2.4)	0		1	(0.8)
MILD	0		0		1		0		1	
歯冠周囲炎	0		1	(2.4)	0		0		1	(0.8)
MODERATE	0		1		0		0		1	
レンサ球菌性咽頭炎	0		1	(2.4)	0		0		1	(0.8)
MODERATE	0		1		0		0		1	
術後創感染	0		0		1	(2.4)	0		1	(0.8)
MILD	0		0		1		0		1	
腎盂腎炎	0		0		0		1	(2.4)	1	(0.8)
MODERATE	0		0		0		1		1	

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	PLACEBO (N=40) n (%)	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=42) n (%)	TOTAL (N=126) n (%)
膿疱性皮疹	0	1 (2.4)	2 (4.8)	0	3 (2.4)
MILD	0	1	2	0	3
鼻炎	1 (2.5)	0	1 (2.4)	1 (2.4)	2 (1.6)
MILD	1	0	1	1	2
副鼻腔炎	0	0	1 (2.4)	1 (2.4)	2 (1.6)
MILD	0	0	0	1	1
MODERATE	0	0	1	0	1
皮膚感染	1 (2.5)	2 (4.8)	0	0	2 (1.6)
MODERATE	1	2	0	0	2
ブドウ球菌感染	0	1 (2.4)	0	0	1 (0.8)
MODERATE	0	1	0	0	1
歯感染	0	0	1 (2.4)	1 (2.4)	2 (1.6)
MILD	0	0	1	0	1
MODERATE	0	0	0	1	1
上気道感染	4 (10.0)	7 (16.7)	5 (11.9)	5 (11.9)	17 (13.5)
MILD	2	5	4	4	13
MODERATE	2	2	1	1	4
尿路感染	0	2 (4.8)	2 (4.8)	1 (2.4)	5 (4.0)
MILD	0	2	2	1	5
ウイルス性上気道感染	0	0	0	1 (2.4)	1 (0.8)
MILD	0	0	0	1	1
外陰腟真菌感染	0	0	0	1 (2.4)	1 (0.8)
MILD	0	0	0	1	1
SUBJECTS WITH ONE OR MORE EVENTS	9 (22.5)	22 (52.4)	18 (42.9)	17 (40.5)	57 (45.2)
MILD	5	13	11	12	36
MODERATE	4	9	6	5	20
SEVERE	0	0	1	0	1

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	PLACEBO (N=40) n (%)	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=42) n (%)	TOTAL (N=126) n (%)
傷害、中毒および処置合併症					
節足動物咬傷	0	1 (2.4)	1 (2.4)	0	2 (1.6)
MILD	0	1	0	0	1
MODERATE	0	0	1	0	1
挫傷	0	0	0	1 (2.4)	1 (0.8)
MODERATE	0	0	0	1	1
顔面損傷	0	0	0	1 (2.4)	1 (0.8)
MODERATE	0	0	0	1	1
転倒	1 (2.5)	0	0	0	0
MILD	1	0	0	0	0
靭帯捻挫	2 (5.0)	0	0	0	0
MILD	2	0	0	0	0
四肢損傷	0	0	0	1 (2.4)	1 (0.8)
MILD	0	0	0	1	1
外傷後頚部症候群	0	1 (2.4)	0	0	1 (0.8)
MILD	0	1	0	0	1
交通事故	0	1 (2.4)	0	1 (2.4)	2 (1.6)
MILD	0	1	0	1	2
皮膚裂傷	0	0	1 (2.4)	2 (4.8)	3 (2.4)
MILD	0	0	1	1	2
MODERATE	0	0	0	1	1
サンバーン	0	0	0	1 (2.4)	1 (0.8)
MILD	0	0	0	1	1
歯牙破折	0	1 (2.4)	0	0	1 (0.8)
MILD	0	1	0	0	1
SUBJECTS WITH ONE OR MORE EVENTS	3 (7.5)	3 (7.1)	2 (4.8)	5 (11.9)	10 (7.9)
MILD	3	3	1	2	6
MODERATE	0	0	1	3	4

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	PLACEBO (N=40) n (%)	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=42) n (%)	UPA TOTAL (N=126) n (%)
臨床検査					
アラニンアミノトランスフェラーゼ増加	1 (2.5)	0	0	0	0
MILD	1	0	0	0	0
アスパラギン酸アミノトランスフェラーゼ増加	1 (2.5)	0	0	0	0
MILD	1	0	0	0	0
血中ビリルビン増加	0	0	1 (2.4)	0	1 (0.8)
MILD	0	0	1	0	1
血中コレステロール増加	0	0	0	1 (2.4)	1 (0.8)
MILD	0	0	0	1	1
血中クレアチン増加	1 (2.5)	0	0	0	0
MILD	1	0	0	0	0
血中クレアチンホスホキナーゼ増加	2 (5.0)	0	3 (7.1)	4 (9.5)	7 (5.6)
MILD	1	0	2	3	5
MODERATE	1	0	1	1	2
血中テストステロン減少	0	0	1 (2.4)	0	1 (0.8)
MODERATE	0	0	1	0	1
血中トリグリセリド増加	0	0	1 (2.4)	1 (2.4)	2 (1.6)
MILD	0	0	1	1	2
子宮頚部スミア異常	0	0	1 (2.4)	0	1 (0.8)
MILD	0	0	1	0	1
体重増加	0	1 (2.4)	0	0	1 (0.8)
MODERATE	0	1	0	0	1
白血球数減少	0	0	1 (2.4)	0	1 (0.8)
MILD	0	0	1	0	1
SUBJECTS WITH ONE OR MORE EVENTS	4 (10.0)	1 (2.4)	7 (16.7)	5 (11.9)	13 (10.3)
MILD	3	0	5	4	9
MODERATE	1	1	2	1	4

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	PLACEBO (N=40) n (%)	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=42) n (%)	UPA TOTAL (N=126) n (%)
代謝および栄養障害					
食欲減退	0	1 (2.4)	0	0	1 (0.8)
MILD	0	1	0	0	1
脱水	0	0	0	1 (2.4)	1 (0.8)
MILD	0	0	0	1	1
高コレステロール血症	0	0	1 (2.4)	0	1 (0.8)
MILD	0	0	1	0	1
高トリグリセリド血症	0	0	0	2 (4.8)	2 (1.6)
MILD	0	0	0	2	2
低ナトリウム血症	1 (2.5)	0	0	0	0
MODERATE	1	0	0	0	0
ビタミンB12欠乏	0	1 (2.4)	0	0	1 (0.8)
MODERATE	0	1	0	0	1
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.5)	2 (4.8)	1 (2.4)	3 (7.1)	6 (4.8)
MILD	0	1	1	3	5
MODERATE	1	1	0	0	1
筋骨格系および結合組織障害					
関節痛	1 (2.5)	1 (2.4)	0	1 (2.4)	2 (1.6)
MILD	1	1	0	1	2
背部痛	1 (2.5)	1 (2.4)	0	0	1 (0.8)
MILD	1	1	0	0	1
筋痙縮	0	0	1 (2.4)	0	1 (0.8)
MILD	0	0	1	0	1
筋骨格系胸痛	0	1 (2.4)	0	1 (2.4)	2 (1.6)
MILD	0	1	0	1	2

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	PLACEBO (N=40) n (%)	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=42) n (%)	UPA TOTAL (N=126) n (%)
筋肉痛	1 (2.5)	0	0	1 (2.4)	1 (0.8)
MILD	1	0	0	1	1
頚部痛	0	0	0	1 (2.4)	1 (0.8)
MILD	0	0	0	1	1
四肢痛	1 (2.5)	0	0	0	0
MILD	1	0	0	0	0
腱障害	0	0	0	1 (2.4)	1 (0.8)
MODERATE	0	0	0	1	1
SUBJECTS WITH ONE OR MORE EVENTS	4 (10.0)	2 (4.8)	1 (2.4)	4 (9.5)	7 (5.6)
MILD	4	2	1	3	6
MODERATE	0	0	0	1	1
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）					
脂漏性角化症	0	0	0	1 (2.4)	1 (0.8)
MODERATE	0	0	0	1	1
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	1 (2.4)	1 (0.8)
MODERATE	0	0	0	1	1
神経系障害					
注意力障害	0	0	1 (2.4)	0	1 (0.8)
MILD	0	0	1	0	1
浮動性めまい	0	0	1 (2.4)	2 (4.8)	3 (2.4)
MILD	0	0	1	2	3
頭痛	1 (2.5)	3 (7.1)	3 (7.1)	4 (9.5)	10 (7.9)
MILD	1	3	2	4	9
MODERATE	0	0	1	0	1

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	PLACEBO (N=40) n (%)	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=42) n (%)	UPA TOTAL (N=126) n (%)
感覚鈍麻	0	0	0	1 (2.4)	1 (0.8)
MILD	0	0	0	1	1
片頭痛	0	1 (2.4)	0	0	1 (0.8)
MILD	0	1	0	0	1
錯感覚	0	0	0	1 (2.4)	1 (0.8)
MILD	0	0	0	1	1
痙攣発作	0	0	1 (2.4)	0	1 (0.8)
MODERATE	0	0	1	0	1
傾眠	0	0	0	1 (2.4)	1 (0.8)
MILD	0	0	0	1	1
失神	0	0	0	1 (2.4)	1 (0.8)
MODERATE	0	0	0	1	1
緊張性頭痛	0	1 (2.4)	0	0	1 (0.8)
MILD	0	1	0	0	1
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.5)	5 (11.9)	5 (11.9)	7 (16.7)	17 (13.5)
MILD	1	5	3	6	14
MODERATE	0	0	2	1	3
精神障害					
錯乱状態	0	0	1 (2.4)	0	1 (0.8)
MILD	0	0	1	0	1
うつ病	0	0	1 (2.4)	0	1 (0.8)
MILD	0	0	1	0	1
不眠症	1 (2.5)	0	0	0	0
MODERATE	1	0	0	0	0
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.5)	0	2 (4.8)	0	2 (1.6)
MILD	0	0	2	0	2

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	PLACEBO (N=40) n (%)	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=42) n (%)	UPA TOTAL (N=126) n (%)
MODERATE	1	0	0	0	0
腎および尿路障害					
血尿	2 (5.0)	0	0	0	0
MILD	2	0	0	0	0
腎症	0	0	0	1 (2.4)	1 (0.8)
MODERATE	0	0	0	1	1
蛋白尿	2 (5.0)	0	0	0	0
MILD	2	0	0	0	0
SUBJECTS WITH ONE OR MORE EVENTS	3 (7.5)	0	0	1 (2.4)	1 (0.8)
MILD	3	0	0	0	0
MODERATE	0	0	0	1	1
生殖系および乳房障害					
無月経	0	0	0	1 (2.4)	1 (0.8)
MILD	0	0	0	1	1
生殖器病変	1 (2.5)	0	0	0	0
MILD	1	0	0	0	0
月経前頭痛	0	0	0	1 (2.4)	1 (0.8)
MILD	0	0	0	1	1
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.5)	0	0	2 (4.8)	2 (1.6)
MILD	1	0	0	2	2
呼吸器、胸郭および縦隔障害					
咳嗽	0	0	1 (2.4)	0	1 (0.8)
MILD	0	0	1	0	1

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	PLACEBO (N=40) n (%)	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=42) n (%)	TOTAL (N=126) n (%)
呼吸困難	0	0	1 (2.4)	0	1 (0.8)
MILD	0	0	1	0	1
鼻出血	0	0	1 (2.4)	0	1 (0.8)
MILD	0	0	1	0	1
口腔咽頭痛	0	3 (7.1)	0	0	3 (2.4)
MILD	0	3	0	0	3
湿性咳嗽	0	1 (2.4)	0	0	1 (0.8)
MILD	0	1	0	0	1
肺腫瘤	1 (2.5)	0	0	0	0
MILD	1	0	0	0	0
アレルギー性鼻炎	1 (2.5)	0	0	0	0
MODERATE	1	0	0	0	0
副鼻腔うっ血	0	0	0	1 (2.4)	1 (0.8)
MILD	0	0	0	1	1
SUBJECTS WITH ONE OR MORE EVENTS	2 (5.0)	3 (7.1)	2 (4.8)	1 (2.4)	6 (4.8)
MILD	1	3	2	1	6
MODERATE	1	0	0	0	0
皮膚および皮下組織障害					
ざ瘡	1 (2.5)	4 (9.5)	2 (4.8)	6 (14.3)	12 (9.5)
MILD	1	3	1	4	8
MODERATE	0	1	1	2	4
脱毛症	1 (2.5)	0	0	0	0
MILD	1	0	0	0	0
ざ瘡様皮膚炎	0	0	1 (2.4)	0	1 (0.8)
MILD	0	0	1	0	1
アトピー性皮膚炎	2 (5.0)	6 (14.3)	2 (4.8)	4 (9.5)	12 (9.5)
MILD	0	2	0	2	4

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	PLACEBO (N=40) n (%)	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=42) n (%)	UPA TOTAL (N=126) n (%)
MODERATE	2	4	2	2	8
接触皮膚炎	2 (5.0)	0	1 (2.4)	1 (2.4)	2 (1.6)
MILD	2	0	1	1	2
皮膚乾燥	1 (2.5)	0	0	0	0
MODERATE	1	0	0	0	0
ケロイド瘢痕	0	0	1 (2.4)	0	1 (0.8)
MILD	0	0	1	0	1
寝汗	0	0	2 (4.8)	0	2 (1.6)
MILD	0	0	1	0	1
MODERATE	0	0	1	0	1
斑状丘疹状皮疹	0	0	1 (2.4)	0	1 (0.8)
MODERATE	0	0	1	0	1
皮膚局面	0	1 (2.4)	0	0	1 (0.8)
MODERATE	0	1	0	0	1
SUBJECTS WITH ONE OR MORE EVENTS	6 (15.0)	10 (23.8)	10 (23.8)	10 (23.8)	30 (23.8)
MILD	3	4	5	6	15
MODERATE	3	6	5	4	15

NOTE: TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS ANY ADVERSE EVENT WITH AN ONSET DATE ON OR AFTER THE FIRST DOSE OF STUDY DRUG IN PERIOD 1 AND PRIOR TO THE FIRST DOSE OF STUDY DRUG IN PERIOD 2 OR UP TO 30 DAYS AFTER THE LAST DOSE OF STUDY DRUG IF SUBJECT DISCONTINUED STUDY DRUG PREMATURELY FROM PERIOD 1 OF THE STUDY.
TABLE DEPICTS THE MOST SEVERE ADVERSE EVENT FOR EACH PREFERRED TERM AS ASSESSED FOR EACH SUBJECT.
THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.

相互参照：M16-048試験 CSR Table 14.3 1.4.1

表 2.7.4.7-34. 全期間（第 1 ピリオド及び第 2 ピリオド）の有害事象の器官別大分類別，基本語別及び最大重症度別の集計結果（Safety 1 集団及び Safety 2 集団）：M16-048 試験

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
ANY ADVERSE EVENT	33 (78.6)	33 (78.6)	88 (77.2)
MILD	17	17	28
MODERATE	16	15	52
SEVERE	0	1	8
血液およびリンパ系障害			
貧血	0	0	3 (2.6)
MILD	0	0	1
MODERATE	0	0	2
内出血発生の増加傾向	0	0	1 (0.9)
MILD	0	0	1
リンパ節炎	0	0	1 (0.9)
MILD	0	0	1
リンパ節症	1 (2.4)	0	2 (1.8)
MILD	1	0	2
リンパ球減少症	0	1 (2.4)	0
MILD	0	1	0
好中球減少症	1 (2.4)	2 (4.8)	3 (2.6)
MILD	0	2	3
MODERATE	1	0	0
SUBJECTS WITH ONE OR MORE EVENTS	2 (4.8)	2 (4.8)	10 (8.8)
MILD	1	2	8
MODERATE	1	0	2

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
心臓障害			
心肺停止	0	0	1 (0.9)
SEVERE	0	0	1
動悸	0	1 (2.4)	0
MILD	0	1	0
心膜炎	0	0	1 (0.9)
SEVERE	0	0	1
洞結節機能不全	0	0	1 (0.9)
MODERATE	0	0	1
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (2.4)	2 (1.8)
MILD	0	1	0
SEVERE	0	0	2
先天性、家族性および遺伝性障害			
角膜ジストロフィー	0	0	1 (0.9)
MODERATE	0	0	1
SUBJECTS WITH ONE OR MORE EVENTS	0	0	1 (0.9)
MODERATE	0	0	1
耳および迷路障害			
耳痛	0	0	1 (0.9)
MILD	0	0	1
回転性めまい	0	1 (2.4)	0
MILD	0	1	0
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (2.4)	1 (0.9)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
MILD	0	1	1
内分泌障害			
甲状腺腫	1 (2.4)	0	0
MILD	1	0	0
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.4)	0	0
MILD	1	0	0
眼障害			
白内障	0	0	1 (0.9)
MODERATE	0	0	1
霰粒腫	1 (2.4)	0	0
MILD	1	0	0
結膜リンパ管拡張症	0	0	1 (0.9)
MILD	0	0	1
アレルギー性結膜炎	0	0	1 (0.9)
MODERATE	0	0	1
ドライアイ	0	1 (2.4)	0
MILD	0	1	0
眼刺激	0	0	1 (0.9)
MILD	0	0	1
虹彩毛様体炎	0	0	1 (0.9)
MODERATE	0	0	1
流涙増加	0	1 (2.4)	1 (0.9)
MILD	0	1	1
瞼板腺炎	0	0	1 (0.9)
MODERATE	0	0	1

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) n (%)		UPA 15 MG QD (N=42) n (%)		UPA 30 MG QD (N=114) n (%)	
点状角膜炎	0		1	(2.4)	0	
MODERATE	0		1		0	
眼瞼腫脹	0		0		1	(0.9)
MILD	0		0		1	
潰瘍性角膜炎	1	(2.4)	0		0	
MODERATE	1		0		0	
ぶどう膜炎	0		0		1	(0.9)
MODERATE	0		0		1	
霧視	0		0		2	(1.8)
MILD	0		0		2	
SUBJECTS WITH ONE OR MORE EVENTS	2	(4.8)	3	(7.1)	8	(7.0)
MILD	1		2		5	
MODERATE	1		1		3	
胃腸障害						
腹痛	0		2	(4.8)	2	(1.8)
MILD	0		2		2	
上腹部痛	0		1	(2.4)	3	(2.6)
MILD	0		1		0	
MODERATE	0		0		3	
便秘	0		0		1	(0.9)
MODERATE	0		0		1	
下痢	2	(4.8)	2	(4.8)	2	(1.8)
MILD	2		2		2	
消化不良	0		0		1	(0.9)
MILD	0		0		1	
変色便	0		1	(2.4)	0	
MILD	0		1		0	

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) n (%)		UPA 15 MG QD (N=42) n (%)		UPA 30 MG QD (N=114) n (%)	
胃炎	0		1	(2.4)	1	(0.9)
MILD	0		1		1	
消化器痛	1	(2.4)	0		0	
MILD	1		0		0	
悪心	3	(7.1)	1	(2.4)	6	(5.3)
MILD	3		1		6	
食道瘻	0		0		1	(0.9)
SEVERE	0		0		1	
流涎過多	0		0		1	(0.9)
MILD	0		0		1	
口蓋垂炎	0		0		1	(0.9)
MODERATE	0		0		1	
SUBJECTS WITH ONE OR MORE EVENTS	3	(7.1)	5	(11.9)	15	(13.2)
MILD	3		5		9	
MODERATE	0		0		5	
SEVERE	0		0		1	
一般・全身障害および投与部位の状態						
無力症	0		0		1	(0.9)
MODERATE	0		0		1	
嚢胞	0		0		1	(0.9)
MILD	0		0		1	
顔面浮腫	0		0		1	(0.9)
MODERATE	0		0		1	
疲労	1	(2.4)	2	(4.8)	3	(2.6)
MILD	1		2		2	
MODERATE	0		0		1	
インフルエンザ様疾患	0		1	(2.4)	0	

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
MILD	0	1	0
倦怠感	0	0	1 (0.9)
MILD	0	0	1
非心臓性胸痛	0	0	1 (0.9)
MILD	0	0	1
浮腫	1 (2.4)	0	1 (0.9)
MILD	1	0	0
MODERATE	0	0	1
末梢性浮腫	0	0	2 (1.8)
MILD	0	0	1
MODERATE	0	0	1
疼痛	0	0	2 (1.8)
MILD	0	0	2
末梢腫脹	1 (2.4)	0	0
MILD	1	0	0
発熱	1 (2.4)	0	3 (2.6)
MILD	1	0	2
MODERATE	0	0	1
SUBJECTS WITH ONE OR MORE EVENTS	3 (7.1)	2 (4.8)	14 (12.3)
MILD	3	2	9
MODERATE	0	0	5
肝胆道系障害			
脂肪肝	0	1 (2.4)	0
MILD	0	1	0
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (2.4)	0
MILD	0	1	0

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
免疫系障害			
過敏症	0	1 (2.4)	0
MILD	0	1	0
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (2.4)	0
MILD	0	1	0
感染症および寄生虫症			
膿瘍	1 (2.4)	0	0
MILD	1	0	0
虫垂炎	0	1 (2.4)	0
SEVERE	0	1	0
体部白癬	0	0	1 (0.9)
MODERATE	0	0	1
ボトリオミセス症	0	0	1 (0.9)
MODERATE	0	0	1
気管支炎	0	0	3 (2.6)
MILD	0	0	2
MODERATE	0	0	1
水疱性膿痂疹	0	0	1 (0.9)
MODERATE	0	0	1
蜂巣炎	0	0	1 (0.9)
MILD	0	0	1
結膜炎	2 (4.8)	0	0
MODERATE	2	0	0
感染性皮膚炎	0	0	1 (0.9)
MILD	0	0	1

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) n (%)		UPA 15 MG QD (N=42) n (%)		UPA 30 MG QD (N=114) n (%)	
憩室炎	0		0		1	(0.9)
MODERATE	0		0		1	
ヘルペス性状湿疹	0		0		2	(1.8)
MODERATE	0		0		1	
SEVERE	0		0		1	
眼感染	1	(2.4)	0		1	(0.9)
MILD	0		0		1	
MODERATE	1		0		0	
毛包炎	2	(4.8)	2	(4.8)	5	(4.4)
MILD	1		1		3	
MODERATE	1		1		2	
皮膚真菌感染	0		0		1	(0.9)
MILD	0		0		1	
胃腸炎	1	(2.4)	1	(2.4)	4	(3.5)
MILD	1		1		2	
MODERATE	0		0		2	
消化管感染	0		0		1	(0.9)
MODERATE	0		0		1	
陰部ヘルペス	0		0		1	(0.9)
MILD	0		0		1	
歯肉炎	0		0		1	(0.9)
MODERATE	0		0		1	
ヘリコバクター感染	0		0		1	(0.9)
MODERATE	0		0		1	
単純ヘルペス	0		2	(4.8)	4	(3.5)
MILD	0		0		2	
MODERATE	0		2		2	
帯状疱疹	0		0		10	(8.8)
MILD	0		0		2	
MODERATE	0		0		7	

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) n (%)		UPA 15 MG QD (N=42) n (%)		UPA 30 MG QD (N=114) n (%)	
SEVERE	0		0		1	
麦粒腫	0		0		2	(1.8)
MILD	0		0		1	
MODERATE	0		0		1	
膿痂疹	1	(2.4)	0		8	(7.0)
MILD	1		0		1	
MODERATE	0		0		6	
SEVERE	0		0		1	
インフルエンザ	3	(7.1)	0		3	(2.6)
MILD	3		0		2	
MODERATE	0		0		1	
下気道感染	0		1	(2.4)	1	(0.9)
MILD	0		1		0	
MODERATE	0		0		1	
細菌性下気道感染	0		0		1	(0.9)
MODERATE	0		0		1	
リンパ管炎	0		1	(2.4)	0	
MODERATE	0		1		0	
伝染性軟属腫	0		0		2	(1.8)
MILD	0		0		1	
MODERATE	0		0		1	
上咽頭炎	3	(7.1)	5	(11.9)	11	(9.6)
MILD	3		3		7	
MODERATE	0		2		4	
口腔ヘルペス	0		1	(2.4)	2	(1.8)
MILD	0		1		1	
MODERATE	0		0		1	
外耳炎	0		1	(2.4)	1	(0.9)
MODERATE	0		1		1	
爪囲炎	0		1	(2.4)	1	(0.9)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) n (%)		UPA 15 MG QD (N=42) n (%)		UPA 30 MG QD (N=114) n (%)	
MILD	0		1		1	
歯冠周囲炎	1	(2.4)	0		0	
MODERATE	1		0		0	
レンサ球菌性咽頭炎	1	(2.4)	0		3	(2.6)
MILD	0		0		2	
MODERATE	1		0		1	
術後創感染	0		1	(2.4)	0	
MILD	0		1		0	
歯髄炎	0		0		1	(0.9)
MODERATE	0		0		1	
腎盂腎炎	0		0		1	(0.9)
MODERATE	0		0		1	
膿疱性皮疹	1	(2.4)	2	(4.8)	0	
MILD	1		2		0	
気道感染	0		0		2	(1.8)
MILD	0		0		2	
鼻炎	0		1	(2.4)	1	(0.9)
MILD	0		1		1	
敗血症	0		0		1	(0.9)
SEVERE	0		0		1	
副鼻腔炎	1	(2.4)	1	(2.4)	3	(2.6)
MILD	1		0		1	
MODERATE	0		1		2	
皮膚感染	3	(7.1)	0		1	(0.9)
MODERATE	3		0		1	
ブドウ球菌感染	1	(2.4)	0		0	
MODERATE	1		0		0	
白癬感染	0		0		1	(0.9)
MILD	0		0		1	
足部白癬	0		0		1	(0.9)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
MILD	0	0	1
癜風	0	0	1 (0.9)
MODERATE	0	0	1
歯感染	0	1 (2.4)	2 (1.8)
MILD	0	1	1
MODERATE	0	0	1
上気道感染	7 (16.7)	7 (16.7)	26 (22.8)
MILD	5	5	16
MODERATE	2	2	10
尿路感染	2 (4.8)	2 (4.8)	6 (5.3)
MILD	2	2	3
MODERATE	0	0	3
ウイルス性上気道感染	0	0	2 (1.8)
MILD	0	0	2
外陰腟真菌感染	0	0	1 (0.9)
MILD	0	0	1
SUBJECTS WITH ONE OR MORE EVENTS	23 (54.8)	21 (50.0)	68 (59.6)
MILD	13	13	28
MODERATE	10	7	37
SEVERE	0	1	3
傷害、中毒および処置合併症			
節足動物咬傷	1 (2.4)	1 (2.4)	0
MILD	1	0	0
MODERATE	0	1	0
挫傷	0	0	2 (1.8)
MILD	0	0	1
MODERATE	0	0	1

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) n (%)		UPA 15 MG QD (N=42) n (%)		UPA 30 MG QD (N=114) n (%)	
顔面損傷	0		0		1	(0.9)
MODERATE	0		0		1	
転倒	0		0		1	(0.9)
MODERATE	0		0		1	
靭帯捻挫	0		0		1	(0.9)
MILD	0		0		1	
四肢損傷	0		0		2	(1.8)
MILD	0		0		1	
MODERATE	0		0		1	
肉離れ	0		0		1	(0.9)
MILD	0		0		1	
眼窩周囲血腫	0		0		1	(0.9)
MILD	0		0		1	
外傷後頚部症候群	1	(2.4)	0		0	
MILD	1		0		0	
処置による疼痛	0		1	(2.4)	0	
MODERATE	0		1		0	
交通事故	1	(2.4)	0		1	(0.9)
MILD	1		0		1	
皮膚裂傷	0		1	(2.4)	3	(2.6)
MILD	0		1		1	
MODERATE	0		0		2	
サンバーン	0		0		1	(0.9)
MILD	0		0		1	
歯牙破折	1	(2.4)	0		0	
MILD	1		0		0	
SUBJECTS WITH ONE OR MORE EVENTS	3	(7.1)	3	(7.1)	10	(8.8)
MILD	3		1		5	
MODERATE	0		2		5	

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) n (%)		UPA 15 MG QD (N=42) n (%)		UPA 30 MG QD (N=114) n (%)	
臨床検査						
血中ビリルビン増加	0		1	(2.4)	0	
MILD	0		1		0	
血中コレステロール増加	0		0		1	(0.9)
MILD	0		0		1	
血中クレアチンホスホキナーゼ増加	0		3	(7.1)	7	(6.1)
MILD	0		2		6	
MODERATE	0		1		1	
血中鉄減少	0		0		1	(0.9)
MILD	0		0		1	
血中テストステロン減少	0		1	(2.4)	0	
MODERATE	0		1		0	
血中トリグリセリド増加	0		1	(2.4)	1	(0.9)
MILD	0		1		1	
血中尿酸増加	0		1	(2.4)	0	
MILD	0		1		0	
心雑音	0		0		1	(0.9)
MILD	0		0		1	
ヘモグロビン減少	0		0		2	(1.8)
MILD	0		0		1	
MODERATE	0		0		1	
肝酵素上昇	0		0		1	(0.9)
MODERATE	0		0		1	
赤血球数減少	0		1	(2.4)	0	
MILD	0		1		0	
子宮頚部スミア異常	0		1	(2.4)	0	
MILD	0		1		0	
体重増加	1	(2.4)	0		0	

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
MODERATE	1	0	0
白血球数減少	0	1 (2.4)	0
MILD	0	1	0
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.4)	8 (19.0)	12 (10.5)
MILD	0	6	9
MODERATE	1	2	3
代謝および栄養障害			
食欲減退	1 (2.4)	0	0
MILD	1	0	0
脱水	0	0	1 (0.9)
MILD	0	0	1
痛風	0	0	1 (0.9)
MILD	0	0	1
高コレステロール血症	0	1 (2.4)	0
MILD	0	1	0
高トリグリセリド血症	0	0	2 (1.8)
MILD	0	0	2
ビタミンB12欠乏	1 (2.4)	0	0
MODERATE	1	0	0
SUBJECTS WITH ONE OR MORE EVENTS	2 (4.8)	1 (2.4)	4 (3.5)
MILD	1	1	4
MODERATE	1	0	0
筋骨格系および結合組織障害			
関節痛	1 (2.4)	0	3 (2.6)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) n (%)		UPA 15 MG QD (N=42) n (%)		UPA 30 MG QD (N=114) n (%)	
MILD	1		0		3	
背部痛	1	(2.4)	0		4	(3.5)
MILD	1		0		3	
MODERATE	0		0		1	
筋痙縮	0		1	(2.4)	0	
MILD	0		1		0	
筋骨格系胸痛	1	(2.4)	0		1	(0.9)
MILD	1		0		1	
筋骨格痛	0		1	(2.4)	1	(0.9)
MILD	0		0		1	
MODERATE	0		1		0	
筋肉痛	0		0		1	(0.9)
MILD	0		0		1	
頚部痛	0		0		1	(0.9)
MILD	0		0		1	
変形性関節症	0		0		1	(0.9)
SEVERE	0		0		1	
足底筋膜炎	0		0		2	(1.8)
MILD	0		0		2	
関節リウマチ	0		0		1	(0.9)
MODERATE	0		0		1	
肩回旋筋腱板症候群	0		0		1	(0.9)
MODERATE	0		0		1	
軟部組織腫脹	0		0		1	(0.9)
MILD	0		0		1	
腱障害	0		0		1	(0.9)
MODERATE	0		0		1	
SUBJECTS WITH ONE OR MORE EVENTS	2	(4.8)	1	(2.4)	14	(12.3)
MILD	2		0		9	

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) n (%)		UPA 15 MG QD (N=42) n (%)		UPA 30 MG QD (N=114) n (%)	
MODERATE	0		1		4	
SEVERE	0		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）						
脂肪腫	0		0		1	(0.9)
MILD	0		0		1	
単クローン性免疫グロブリン血症	0		0		1	(0.9)
MODERATE	0		0		1	
菌状息肉症	0		0		1	(0.9)
MODERATE	0		0		1	
脂漏性角化症	0		0		1	(0.9)
MODERATE	0		0		1	
皮膚乳頭腫	0		1	(2.4)	3	(2.6)
MILD	0		0		2	
MODERATE	0		1		1	
皮膚有棘細胞癌	0		0		1	(0.9)
MILD	0		0		1	
SUBJECTS WITH ONE OR MORE EVENTS	0		1	(2.4)	7	(6.1)
MILD	0		0		3	
MODERATE	0		1		4	
神経系障害						
注意力障害	0		1	(2.4)	0	
MILD	0		1		0	
浮動性めまい	0		1	(2.4)	2	(1.8)
MILD	0		1		2	
頭痛	3	(7.1)	3	(7.1)	7	(6.1)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
MILD	3	2	6
MODERATE	0	1	1
感覚鈍麻	0	0	1 (0.9)
MILD	0	0	1
片頭痛	1 (2.4)	0	1 (0.9)
MILD	1	0	1
錯感覚	0	0	1 (0.9)
MILD	0	0	1
痙攣発作	0	1 (2.4)	0
MODERATE	0	1	0
傾眠	0	0	1 (0.9)
MILD	0	0	1
失神	0	0	1 (0.9)
MODERATE	0	0	1
緊張性頭痛	1 (2.4)	0	0
MILD	1	0	0
SUBJECTS WITH ONE OR MORE EVENTS	5 (11.9)	5 (11.9)	11 (9.6)
MILD	5	3	9
MODERATE	0	2	2
精神障害			
不安	0	1 (2.4)	2 (1.8)
MILD	0	1	1
MODERATE	0	0	1
錯乱状態	0	1 (2.4)	0
MILD	0	1	0
うつ病	0	1 (2.4)	1 (0.9)
MILD	0	1	0

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
MODERATE	0	0	1
不眠症	0	0	2 (1.8)
MILD	0	0	1
MODERATE	0	0	1
SUBJECTS WITH ONE OR MORE EVENTS	0	3 (7.1)	4 (3.5)
MILD	0	3	1
MODERATE	0	0	3
腎および尿路障害			
ビリルビン尿	0	0	1 (0.9)
MILD	0	0	1
血尿	0	0	1 (0.9)
MILD	0	0	1
腎結石症	0	0	1 (0.9)
MODERATE	0	0	1
腎症	0	0	1 (0.9)
MODERATE	0	0	1
蛋白尿	0	0	1 (0.9)
MODERATE	0	0	1
腎嚢胞	0	1 (2.4)	0
MILD	0	1	0
尿管結石症	0	0	1 (0.9)
SEVERE	0	0	1
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (2.4)	6 (5.3)
MILD	0	1	2
MODERATE	0	0	3
SEVERE	0	0	1

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) n (%)		UPA 15 MG QD (N=42) n (%)		UPA 30 MG QD (N=114) n (%)	
生殖系および乳房障害						
無月経	0		0		1	(0.9)
MILD	0		0		1	
勃起不全	0		0		1	(0.9)
MILD	0		0		1	
月経過多	0		0		1	(0.9)
MILD	0		0		1	
月経前頭痛	0		0		1	(0.9)
MILD	0		0		1	
精巣痛	0		0		1	(0.9)
MODERATE	0		0		1	
SUBJECTS WITH ONE OR MORE EVENTS	0		0		5	(4.4)
MILD	0		0		4	
MODERATE	0		0		1	
呼吸器、胸郭および縦隔障害						
喘息	0		1	(2.4)	1	(0.9)
MILD	0		1		0	
MODERATE	0		0		1	
咳嗽	0		1	(2.4)	3	(2.6)
MILD	0		1		3	
呼吸困難	0		1	(2.4)	0	
MILD	0		1		0	
鼻出血	0		1	(2.4)	0	
MILD	0		1		0	
喀血	0		0		1	(0.9)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
MILD	0	0	1
口腔咽頭痛	3 (7.1)	0	0
MILD	3	0	0
湿性咳嗽	1 (2.4)	0	0
MILD	1	0	0
肺塞栓症	0	0	1 (0.9)
SEVERE	0	0	1
副鼻腔うっ血	0	1 (2.4)	1 (0.9)
MILD	0	1	1
睡眠時無呼吸症候群	0	1 (2.4)	0
MODERATE	0	1	0
SUBJECTS WITH ONE OR MORE EVENTS	3 (7.1)	4 (9.5)	7 (6.1)
MILD	3	3	5
MODERATE	0	1	1
SEVERE	0	0	1
皮膚および皮下組織障害			
ざ瘡	4 (9.5)	2 (4.8)	13 (11.4)
MILD	3	1	11
MODERATE	1	1	2
光線角化症	0	0	1 (0.9)
MILD	0	0	1
水疱	0	0	1 (0.9)
MILD	0	0	1
血性水疱	0	0	1 (0.9)
MILD	0	0	1
皮膚嚢腫	0	0	2 (1.8)
MILD	0	0	1

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) n (%)		UPA 15 MG QD (N=42) n (%)		UPA 30 MG QD (N=114) n (%)	
MODERATE	0		0		1	
ざ瘡様皮膚炎	0		1	(2.4)	1	(0.9)
MILD	0		1		1	
アトピー性皮膚炎	7	(16.7)	5	(11.9)	22	(19.3)
MILD	2		1		6	
MODERATE	5		4		15	
SEVERE	0		0		1	
接触皮膚炎	0		1	(2.4)	2	(1.8)
MILD	0		1		2	
多汗症	0		0		1	(0.9)
MILD	0		0		1	
間擦疹	1	(2.4)	0		1	(0.9)
MILD	1		0		1	
ケロイド瘢痕	0		1	(2.4)	0	
MILD	0		1		0	
寝汗	0		2	(4.8)	0	
MILD	0		1		0	
MODERATE	0		1		0	
丘疹膿疱性酒さ	0		0		1	(0.9)
MILD	0		0		1	
光線過敏性反応	0		1	(2.4)	0	
MILD	0		1		0	
ばら色粃糠疹	0		0		1	(0.9)
MILD	0		0		1	
斑状丘疹状皮疹	0		1	(2.4)	0	
MODERATE	0		1		0	
酒さ	1	(2.4)	0		1	(0.9)
MODERATE	1		0		1	
皮膚不快感	0		0		1	(0.9)
MODERATE	0		0		1	

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
皮膚剥脱	0	1 (2.4)	1 (0.9)
MILD	0	1	1
皮膚刺激	0	0	1 (0.9)
MILD	0	0	1
皮膚局面	1 (2.4)	0	0
MODERATE	1	0	0
蕁麻疹	0	0	3 (2.6)
MODERATE	0	0	3
SUBJECTS WITH ONE OR MORE EVENTS	12 (28.6)	13 (31.0)	39 (34.2)
MILD	4	6	19
MODERATE	8	7	19
SEVERE	0	0	1
血管障害			
高血圧	1 (2.4)	0	2 (1.8)
MILD	0	0	2
MODERATE	1	0	0
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.4)	0	2 (1.8)
MILD	0	0	2
MODERATE	1	0	0

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) n (%)	 15 MG QD (N=42) n (%)	 30 MG QD (N=114) n (%)

NOTE: TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS ANY ADVERSE EVENT WITH AN ONSET DATE ON OR AFTER THE FIRST DOSE OF UPA AND UP TO 30 DAYS AFTER THE LAST DOSE OF UPA. ANY ADVERSE EVENT WITH AN ONSET DATE ON OR AFTER THE FIRST DOSE OF UPA 30 MG RESCUE THERAPHY WILL BE COUNTED INTO UPA 30 MG GROUP. A PATIENT RECEIVING RESCUE THERAPHY AFTER UPA 7.5 MG/15 MG TREATMENT WILL BE COUNTED IN THE DENOMINATORS OF BOTH 7.5 MG/15 MG AND 30 MG DOSE GROUPS.
TABLE DEPICTS THE MOST SEVERE ADVERSE EVENT FOR EACH PREFERRED TERM AS ASSESSED FOR EACH SUBJECT WITHIN EACH TREATMENT GROUP.
THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WITHIN EACH TREATMENT GROUP WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.

相互参照：M16-048試験 CSR Table 14.3 1.4.2

表 2.7.4.7-35. 全期間（第 1 ピリオド及び第 2 ピリオド）の 100 人年あたりの有害事象の器官別大分類別，基本語別及び重症度別の集計結果（Safety 1 集団及び Safety 2 集団）：M16-048 試験

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
ANY ADVERSE EVENT	86 (565.8)	109 (526.6)	399 (305.7)
MILD	61	80	231
MODERATE	25	28	157
SEVERE	0	1	11
血液およびリンパ系障害			
貧血	0	0	3 (2.3)
MILD	0	0	1
MODERATE	0	0	2
内出血発生の増加傾向	0	0	1 (0.8)
MILD	0	0	1
リンパ節炎	0	0	1 (0.8)
MILD	0	0	1
リンパ節症	1 (6.6)	0	3 (2.3)
MILD	1	0	3
リンパ球減少症	0	1 (4.8)	0
MILD	0	1	0
好中球減少症	1 (6.6)	2 (9.7)	3 (2.3)
MILD	0	2	3
MODERATE	1	0	0
TOTAL EVENTS	2 (13.2)	3 (14.5)	11 (8.4)
MILD	1	3	9
MODERATE	1	0	2

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
心臓障害			
心肺停止	0	0	1 (0.8)
SEVERE	0	0	1
動悸	0	1 (4.8)	0
MILD	0	1	0
心膜炎	0	0	1 (0.8)
SEVERE	0	0	1
洞結節機能不全	0	0	1 (0.8)
MODERATE	0	0	1
TOTAL EVENTS	0	1 (4.8)	3 (2.3)
MILD	0	1	0
MODERATE	0	0	1
SEVERE	0	0	2
先天性、家族性および遺伝性障害			
角膜ジストロフィー	0	0	1 (0.8)
MODERATE	0	0	1
TOTAL EVENTS	0	0	1 (0.8)
MODERATE	0	0	1
耳および迷路障害			
耳痛	0	0	1 (0.8)
MILD	0	0	1
回転性めまい	0	1 (4.8)	0
MILD	0	1	0

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
TOTAL EVENTS	0	1 (4.8)	1 (0.8)
MILD	0	1	1
内分泌障害			
甲状腺腫	1 (6.6)	0	0
MILD	1	0	0
TOTAL EVENTS	1 (6.6)	0	0
MILD	1	0	0
眼障害			
白内障	0	0	1 (0.8)
MODERATE	0	0	1
霰粒腫	1 (6.6)	0	0
MILD	1	0	0
結膜リンパ管拡張症	0	0	1 (0.8)
MILD	0	0	1
アレルギー性結膜炎	0	0	1 (0.8)
MODERATE	0	0	1
ドライアイ	0	1 (4.8)	0
MILD	0	1	0
眼刺激	0	0	2 (1.5)
MILD	0	0	2
虹彩毛様体炎	0	0	1 (0.8)
MODERATE	0	0	1
流涙増加	0	1 (4.8)	1 (0.8)
MILD	0	1	1

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
瞼板腺炎	0	0	1 (0.8)
MODERATE	0	0	1
点状角膜炎	0	1 (4.8)	0
MODERATE	0	1	0
眼瞼腫脹	0	0	1 (0.8)
MILD	0	0	1
潰瘍性角膜炎	1 (6.6)	0	0
MODERATE	1	0	0
ぶどう膜炎	0	0	1 (0.8)
MODERATE	0	0	1
霧視	0	0	2 (1.5)
MILD	0	0	2
TOTAL EVENTS	2 (13.2)	3 (14.5)	12 (9.2)
MILD	1	2	7
MODERATE	1	1	5
胃腸障害			
腹痛	0	2 (9.7)	4 (3.1)
MILD	0	2	4
上腹部痛	0	2 (9.7)	3 (2.3)
MILD	0	2	0
MODERATE	0	0	3
便秘	0	0	1 (0.8)
MODERATE	0	0	1
下痢	2 (13.2)	5 (24.2)	2 (1.5)
MILD	2	5	2
消化不良	0	0	1 (0.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
MILD	0	0	1
変色便	0	1 (4.8)	0
MILD	0	1	0
胃炎	0	1 (4.8)	1 (0.8)
MILD	0	1	1
消化器痛	1 (6.6)	0	0
MILD	1	0	0
悪心	3 (19.7)	1 (4.8)	8 (6.1)
MILD	3	1	8
食道瘻	0	0	1 (0.8)
SEVERE	0	0	1
流涎過多	0	0	1 (0.8)
MILD	0	0	1
口蓋垂炎	0	0	1 (0.8)
MODERATE	0	0	1
TOTAL EVENTS	6 (39.5)	12 (58.0)	23 (17.6)
MILD	6	12	17
MODERATE	0	0	5
SEVERE	0	0	1
一般・全身障害および投与部位の状態			
無力症	0	0	1 (0.8)
MODERATE	0	0	1
嚢胞	0	0	1 (0.8)
MILD	0	0	1
顔面浮腫	0	0	1 (0.8)
MODERATE	0	0	1

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
疲労	1 (6.6)	3 (14.5)	3 (2.3)
MILD	1	3	2
MODERATE	0	0	1
インフルエンザ様疾患	0	3 (14.5)	0
MILD	0	3	0
倦怠感	0	0	1 (0.8)
MILD	0	0	1
非心臓性胸痛	0	0	1 (0.8)
MILD	0	0	1
浮腫	1 (6.6)	0	1 (0.8)
MILD	1	0	0
MODERATE	0	0	1
末梢性浮腫	0	0	2 (1.5)
MILD	0	0	1
MODERATE	0	0	1
疼痛	0	0	2 (1.5)
MILD	0	0	2
末梢腫脹	1 (6.6)	0	0
MILD	1	0	0
発熱	1 (6.6)	0	3 (2.3)
MILD	1	0	2
MODERATE	0	0	1
TOTAL EVENTS	4 (26.3)	6 (29.0)	16 (12.3)
MILD	4	6	10
MODERATE	0	0	6

肝胆道系障害

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
脂肪肝	0	1 (4.8)	0
MILD	0	1	0
TOTAL EVENTS	0	1 (4.8)	0
MILD	0	1	0
免疫系障害			
過敏症	0	1 (4.8)	0
MILD	0	1	0
TOTAL EVENTS	0	1 (4.8)	0
MILD	0	1	0
感染症および寄生虫症			
膿瘍	1 (6.6)	0	0
MILD	1	0	0
虫垂炎	0	1 (4.8)	0
SEVERE	0	1	0
体部白癬	0	0	1 (0.8)
MODERATE	0	0	1
ボトリオミセス症	0	0	2 (1.5)
MODERATE	0	0	2
気管支炎	0	0	3 (2.3)
MILD	0	0	2
MODERATE	0	0	1
水疱性膿痂疹	0	0	1 (0.8)
MODERATE	0	0	1

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
蜂巣炎	0	0	1 (0.8)
MILD	0	0	1
結膜炎	2 (13.2)	0	0
MODERATE	2	0	0
感染性皮膚炎	0	0	1 (0.8)
MILD	0	0	1
憩室炎	0	0	1 (0.8)
MODERATE	0	0	1
ヘルペス性状湿疹	0	0	2 (1.5)
MODERATE	0	0	1
SEVERE	0	0	1
眼感染	2 (13.2)	0	1 (0.8)
MILD	1	0	1
MODERATE	1	0	0
毛包炎	2 (13.2)	2 (9.7)	8 (6.1)
MILD	1	1	3
MODERATE	1	1	5
皮膚真菌感染	0	0	3 (2.3)
MILD	0	0	3
胃腸炎	1 (6.6)	1 (4.8)	4 (3.1)
MILD	1	1	2
MODERATE	0	0	2
消化管感染	0	0	1 (0.8)
MODERATE	0	0	1
陰部ヘルペス	0	0	1 (0.8)
MILD	0	0	1
歯肉炎	0	0	1 (0.8)
MODERATE	0	0	1
ヘリコバクター感染	0	0	1 (0.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
MODERATE	0	0	1
単純ヘルペス	0	2 (9.7)	7 (5.4)
MILD	0	0	4
MODERATE	0	2	3
帯状疱疹	0	0	10 (7.7)
MILD	0	0	2
MODERATE	0	0	7
SEVERE	0	0	1
麦粒腫	0	0	2 (1.5)
MILD	0	0	1
MODERATE	0	0	1
膿痂疹	1 (6.6)	0	8 (6.1)
MILD	1	0	1
MODERATE	0	0	6
SEVERE	0	0	1
インフルエンザ	3 (19.7)	0	4 (3.1)
MILD	3	0	3
MODERATE	0	0	1
下気道感染	0	1 (4.8)	2 (1.5)
MILD	0	1	0
MODERATE	0	0	2
細菌性下気道感染	0	0	1 (0.8)
MODERATE	0	0	1
リンパ管炎	0	1 (4.8)	0
MODERATE	0	1	0
伝染性軟属腫	0	0	3 (2.3)
MILD	0	0	1
MODERATE	0	0	2
上咽頭炎	3 (19.7)	6 (29.0)	16 (12.3)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)		UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)		UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)	
MILD	3		3		10	
MODERATE	0		3		6	
口腔ヘルペス	0		1	(4.8)	3	(2.3)
MILD	0		1		2	
MODERATE	0		0		1	
外耳炎	0		1	(4.8)	1	(0.8)
MODERATE	0		1		1	
爪囲炎	0		1	(4.8)	1	(0.8)
MILD	0		1		1	
歯冠周囲炎	1	(6.6)	0		0	
MODERATE	1		0		0	
レンサ球菌性咽頭炎	1	(6.6)	0		3	(2.3)
MILD	0		0		2	
MODERATE	1		0		1	
術後創感染	0		1	(4.8)	0	
MILD	0		1		0	
歯髄炎	0		0		1	(0.8)
MODERATE	0		0		1	
腎盂腎炎	0		0		1	(0.8)
MODERATE	0		0		1	
膿疱性皮疹	1	(6.6)	2	(9.7)	0	
MILD	1		2		0	
気道感染	0		0		2	(1.5)
MILD	0		0		2	
鼻炎	0		1	(4.8)	1	(0.8)
MILD	0		1		1	
敗血症	0		0		1	(0.8)
SEVERE	0		0		1	
副鼻腔炎	1	(6.6)	1	(4.8)	3	(2.3)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
MILD	1	0	1
MODERATE	0	1	2
皮膚感染	4 (26.3)	0	8 (6.1)
MILD	1	0	0
MODERATE	3	0	8
ブドウ球菌感染	1 (6.6)	0	0
MODERATE	1	0	0
白癬感染	0	0	2 (1.5)
MILD	0	0	2
足部白癬	0	0	1 (0.8)
MILD	0	0	1
癜風	0	0	1 (0.8)
MODERATE	0	0	1
歯感染	0	1 (4.8)	2 (1.5)
MILD	0	1	1
MODERATE	0	0	1
上気道感染	7 (46.1)	7 (33.8)	47 (36.0)
MILD	5	5	29
MODERATE	2	2	18
尿路感染	2 (13.2)	2 (9.7)	8 (6.1)
MILD	2	2	4
MODERATE	0	0	4
ウイルス性上気道感染	0	0	2 (1.5)
MILD	0	0	2
外陰腟真菌感染	0	0	1 (0.8)
MILD	0	0	1
TOTAL EVENTS	33 (217.1)	32 (154.6)	174 (133.3)
MILD	21	20	85

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)		UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)		UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)	
MODERATE	12		11		85	
SEVERE	0		1		4	
傷害、中毒および処置合併症						
節足動物咬傷	1	(6.6)	1	(4.8)	0	
MILD	1		0		0	
MODERATE	0		1		0	
挫傷	0		0		2	(1.5)
MILD	0		0		1	
MODERATE	0		0		1	
顔面損傷	0		0		1	(0.8)
MODERATE	0		0		1	
転倒	0		0		1	(0.8)
MODERATE	0		0		1	
靭帯捻挫	0		0		1	(0.8)
MILD	0		0		1	
四肢損傷	0		0		2	(1.5)
MILD	0		0		1	
MODERATE	0		0		1	
肉離れ	0		0		1	(0.8)
MILD	0		0		1	
眼窩周囲血腫	0		0		1	(0.8)
MILD	0		0		1	
外傷後頚部症候群	1	(6.6)	0		0	
MILD	1		0		0	
処置による疼痛	0		1	(4.8)	0	
MODERATE	0		1		0	
交通事故	1	(6.6)	0		1	(0.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
MILD	1	0	1
皮膚裂傷	0	1 (4.8)	3 (2.3)
MILD	0	1	1
MODERATE	0	0	2
サンバーン	0	0	1 (0.8)
MILD	0	0	1
歯牙破折	1 (6.6)	0	0
MILD	1	0	0
TOTAL EVENTS	4 (26.3)	3 (14.5)	14 (10.7)
MILD	4	1	8
MODERATE	0	2	6
臨床検査			
血中ビリルビン増加	0	1 (4.8)	0
MILD	0	1	0
血中コレステロール増加	0	0	1 (0.8)
MILD	0	0	1
血中クレアチンホスホキナーゼ増加	0	3 (14.5)	8 (6.1)
MILD	0	2	7
MODERATE	0	1	1
血中鉄減少	0	0	1 (0.8)
MILD	0	0	1
血中テストステロン減少	0	1 (4.8)	0
MODERATE	0	1	0
血中トリグリセリド増加	0	1 (4.8)	1 (0.8)
MILD	0	1	1
血中尿酸増加	0	1 (4.8)	0

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
MILD	0	1	0
心雑音	0	0	1 (0.8)
MILD	0	0	1
ヘモグロビン減少	0	0	2 (1.5)
MILD	0	0	1
MODERATE	0	0	1
肝酵素上昇	0	0	1 (0.8)
MODERATE	0	0	1
赤血球数減少	0	1 (4.8)	0
MILD	0	1	0
子宮頚部スミア異常	0	1 (4.8)	0
MILD	0	1	0
体重増加	1 (6.6)	0	0
MODERATE	1	0	0
白血球数減少	0	1 (4.8)	0
MILD	0	1	0
TOTAL EVENTS	1 (6.6)	10 (48.3)	15 (11.5)
MILD	0	8	12
MODERATE	1	2	3
代謝および栄養障害			
食欲減退	1 (6.6)	0	0
MILD	1	0	0
脱水	0	0	1 (0.8)
MILD	0	0	1
痛風	0	0	1 (0.8)
MILD	0	0	1

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
高コレステロール血症	0	1 (4.8)	0
MILD	0	1	0
高トリグリセリド血症	0	0	3 (2.3)
MILD	0	0	3
ビタミンB12欠乏	1 (6.6)	0	0
MODERATE	1	0	0
TOTAL EVENTS	2 (13.2)	1 (4.8)	5 (3.8)
MILD	1	1	5
MODERATE	1	0	0
筋骨格系および結合組織障害			
関節痛	1 (6.6)	0	3 (2.3)
MILD	1	0	3
背部痛	1 (6.6)	0	4 (3.1)
MILD	1	0	3
MODERATE	0	0	1
筋痙縮	0	1 (4.8)	0
MILD	0	1	0
筋骨格系胸痛	1 (6.6)	0	1 (0.8)
MILD	1	0	1
筋骨格痛	0	1 (4.8)	1 (0.8)
MILD	0	0	1
MODERATE	0	1	0
筋肉痛	0	0	1 (0.8)
MILD	0	0	1
頚部痛	0	0	1 (0.8)
MILD	0	0	1

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
変形性関節症	0	0	1 (0.8)
SEVERE	0	0	1
足底筋膜炎	0	0	2 (1.5)
MILD	0	0	2
関節リウマチ	0	0	1 (0.8)
MODERATE	0	0	1
肩回旋筋腱板症候群	0	0	1 (0.8)
MODERATE	0	0	1
軟部組織腫脹	0	0	1 (0.8)
MILD	0	0	1
腱障害	0	0	1 (0.8)
MODERATE	0	0	1
TOTAL EVENTS	3 (19.7)	2 (9.7)	18 (13.8)
MILD	3	1	13
MODERATE	0	1	4
SEVERE	0	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）			
脂肪腫	0	0	1 (0.8)
MILD	0	0	1
単クローン性免疫グロブリン血症	0	0	1 (0.8)
MODERATE	0	0	1
菌状息肉症	0	0	1 (0.8)
MODERATE	0	0	1
脂漏性角化症	0	0	1 (0.8)
MODERATE	0	0	1
皮膚乳頭腫	0	1 (4.8)	3 (2.3)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
MILD	0	0	2
MODERATE	0	1	1
皮膚有棘細胞癌	0	0	1 (0.8)
MILD	0	0	1
TOTAL EVENTS	0	1 (4.8)	8 (6.1)
MILD	0	0	4
MODERATE	0	1	4
神経系障害			
注意力障害	0	1 (4.8)	0
MILD	0	1	0
浮動性めまい	0	1 (4.8)	2 (1.5)
MILD	0	1	2
頭痛	3 (19.7)	3 (14.5)	7 (5.4)
MILD	3	2	6
MODERATE	0	1	1
感覚鈍麻	0	0	1 (0.8)
MILD	0	0	1
片頭痛	1 (6.6)	0	1 (0.8)
MILD	1	0	1
錯感覚	0	0	1 (0.8)
MILD	0	0	1
痙攣発作	0	1 (4.8)	0
MODERATE	0	1	0
傾眠	0	0	1 (0.8)
MILD	0	0	1
失神	0	0	1 (0.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
MODERATE	0	0	1
緊張性頭痛	1 (6.6)	0	0
MILD	1	0	0
TOTAL EVENTS	5 (32.9)	6 (29.0)	14 (10.7)
MILD	5	4	12
MODERATE	0	2	2
精神障害			
不安	0	1 (4.8)	2 (1.5)
MILD	0	1	1
MODERATE	0	0	1
錯乱状態	0	1 (4.8)	0
MILD	0	1	0
うつ病	0	1 (4.8)	2 (1.5)
MILD	0	1	0
MODERATE	0	0	2
不眠症	0	0	2 (1.5)
MILD	0	0	1
MODERATE	0	0	1
TOTAL EVENTS	0	3 (14.5)	6 (4.6)
MILD	0	3	2
MODERATE	0	0	4
腎および尿路障害			
ビリルビン尿	0	0	1 (0.8)
MILD	0	0	1

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
血尿	0	0	1 (0.8)
MILD	0	0	1
腎結石症	0	0	1 (0.8)
MODERATE	0	0	1
腎症	0	0	1 (0.8)
MODERATE	0	0	1
蛋白尿	0	0	1 (0.8)
MODERATE	0	0	1
腎嚢胞	0	1 (4.8)	0
MILD	0	1	0
尿管結石症	0	0	1 (0.8)
SEVERE	0	0	1
TOTAL EVENTS	0	1 (4.8)	6 (4.6)
MILD	0	1	2
MODERATE	0	0	3
SEVERE	0	0	1
生殖系および乳房障害			
無月経	0	0	1 (0.8)
MILD	0	0	1
勃起不全	0	0	1 (0.8)
MILD	0	0	1
月経過多	0	0	1 (0.8)
MILD	0	0	1
月経前頭痛	0	0	1 (0.8)
MILD	0	0	1
精巣痛	0	0	1 (0.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
MODERATE	0	0	1
TOTAL EVENTS	0	0	5 (3.8)
MILD	0	0	4
MODERATE	0	0	1
呼吸器、胸郭および縦隔障害			
喘息	0	1 (4.8)	1 (0.8)
MILD	0	1	0
MODERATE	0	0	1
咳嗽	0	2 (9.7)	3 (2.3)
MILD	0	2	3
呼吸困難	0	1 (4.8)	0
MILD	0	1	0
鼻出血	0	1 (4.8)	0
MILD	0	1	0
喀血	0	0	1 (0.8)
MILD	0	0	1
口腔咽頭痛	3 (19.7)	0	0
MILD	3	0	0
湿性咳嗽	1 (6.6)	0	0
MILD	1	0	0
肺塞栓症	0	0	1 (0.8)
SEVERE	0	0	1
副鼻腔うっ血	0	1 (4.8)	1 (0.8)
MILD	0	1	1
睡眠時無呼吸症候群	0	1 (4.8)	0
MODERATE	0	1	0

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
TOTAL EVENTS	4 (26.3)	7 (33.8)	7 (5.4)
MILD	4	6	5
MODERATE	0	1	1
SEVERE	0	0	1
皮膚および皮下組織障害			
ざ瘡	6 (39.5)	2 (9.7)	14 (10.7)
MILD	5	1	12
MODERATE	1	1	2
光線角化症	0	0	1 (0.8)
MILD	0	0	1
水疱	0	0	1 (0.8)
MILD	0	0	1
血性水疱	0	0	1 (0.8)
MILD	0	0	1
皮膚嚢腫	0	0	2 (1.5)
MILD	0	0	1
MODERATE	0	0	1
ざ瘡様皮膚炎	0	1 (4.8)	1 (0.8)
MILD	0	1	1
アトピー性皮膚炎	9 (59.2)	5 (24.2)	25 (19.2)
MILD	4	1	8
MODERATE	5	4	16
SEVERE	0	0	1
接触皮膚炎	0	1 (4.8)	2 (1.5)
MILD	0	1	2
多汗症	0	0	1 (0.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)		UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)		UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)	
MILD	0		0		1	
間擦疹	1	(6.6)	0		1	(0.8)
MILD	1		0		1	
ケロイド瘢痕	0		1	(4.8)	0	
MILD	0		1		0	
寝汗	0		2	(9.7)	0	
MILD	0		1		0	
MODERATE	0		1		0	
丘疹膿疱性酒さ	0		0		1	(0.8)
MILD	0		0		1	
光線過敏性反応	0		1	(4.8)	0	
MILD	0		1		0	
ばら色粃糠疹	0		0		1	(0.8)
MILD	0		0		1	
斑状丘疹状皮疹	0		1	(4.8)	0	
MODERATE	0		1		0	
酒さ	1	(6.6)	0		1	(0.8)
MODERATE	1		0		1	
皮膚不快感	0		0		1	(0.8)
MODERATE	0		0		1	
皮膚剥脱	0		1	(4.8)	1	(0.8)
MILD	0		1		1	
皮膚刺激	0		0		1	(0.8)
MILD	0		0		1	
皮膚局面	1	(6.6)	0		0	
MODERATE	1		0		0	
蕁麻疹	0		0		3	(2.3)
MODERATE	0		0		3	

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM SEVERITY	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
TOTAL EVENTS	18 (118.4)	15 (72.5)	58 (44.4)
MILD	10	8	33
MODERATE	8	7	24
SEVERE	0	0	1
血管障害			
高血圧	1 (6.6)	0	2 (1.5)
MILD	0	0	2
MODERATE	1	0	0
TOTAL EVENTS	1 (6.6)	0	2 (1.5)
MILD	0	0	2
MODERATE	1	0	0

NOTE: TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS ANY ADVERSE EVENT WITH AN ONSET DATE ON OR AFTER THE FIRST DOSE OF UPA AND UP TO 30 DAYS AFTER THE LAST DOSE OF UPA. ANY ADVERSE EVENT WITH AN ONSET DATE ON OR AFTER THE FIRST DOSE OF UPA 30 MG RESCUE THERAPHY WILL BE COUNTED INTO UPA 30 MG GROUP. A PATIENT RECEIVING RESCUE THERAPHY AFTER UPA 7.5 MG/15 MG TREATMENT WILL BE IN THE DENOMINATORS OF BOTH 7.5 MG/15 MG AND 30 MG DOSE GROUPS.
TABLE DEPICTS THE MOST SEVERE ADVERSE EVENT FOR EACH PREFERRED TERM AS ASSESSED FOR EACH SUBJECT WITHIN EACH TREATMENT GROUP.
E/100PY = EVENTS PER 100 PATIENT-YEARS.

相互参照：M16-048試験 CSR Table 14.3 1.4.3

表 2.7.4.7-36. 全試験期間中の死亡に至った有害事象の一覧表（Safety 1 集団）：M16-048 試験

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset/ Switch	R: Reported Term S: System Organ Class P: MedDRA 21.1 Preferred Term L: Lower Level Term	E: RX Day ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serous AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: PLACEBO/ABT-494 30 MG QD [redacted] AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:105.2 KG								
	P2	112 TO 195	83	194	R:ESOPHAGEAL FISTULA, SEPSIS, PERICARDITIS S: 胃腸障害 P: 食道瘻 L:ESOPHAGEAL FISTULA	E:332 L:139 DAYS	S:SEVERE R:REASONABLE POSSIBILITY A:DRUG WITHDRAWN O:DISCONTINUED STUDY	S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION, LIFE THREATENING, DEATH OF SUBJECT O:ESOPHAGEAL PERFORATION SECONDARY TO ROUTINE SCHEDULED CARDIAC ABLATION RESULTING IN SEPSIS, PERICARDITIS, PLEURAL EFFUSION, AND RENAL FAILURE A:NO REASONABLE POSSIBILITY
				194	S: 心臓障害 P: 心膜炎 L:PERICARDITIS	---------- S A M E A S A B O V E ----------		

Subject Number	------ Name	Epoch	---- Interval	RX Day of Onset/ Switch	R: Reported Term S: System Organ Class P: MedDRA 21.1 Preferred Term L: Lower Level Term	E: RX Day ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serous AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: PLACEBO/ABT-494 30 MG QD [redacted] AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:105.2 KG								
(CONT.)	P2	112 TO 195	83	194	S: 感染症および寄生虫症 P: 敗血症 L:SEPSIS	---------- S A M E A S A B O V E ----------		
INV: [redacted] ([redacted]) TRT: ABT-494 30 MG QD/PLACEBO [redacted] AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:76.4 KG								
	POST	392 TO	2	393	R:CARDIOPULMONARY ARREST S: 心臓障害 P: 心肺停止 L:CARDIOPULMONARY ARREST	E:393 L:1 DAY I:NO	S:SEVERE R:REASONABLE POSSIBILITY O:SUBJECT IS DECEASED	S:YES, LIFE THREATENING, DEATH OF SUBJECT A:NO REASONABLE POSSIBILITY

P1 = PERIOD 1 TREATMENT; P2 = PERIOD 2 TREATMENT; P2R = PERIOD 2 AFTER INITIATING THE RESCUE TREATMENT WITH UPA 30 MG; POST = POST STUDY DRUG.
# SUBJECT PREMATURELY DISCONTINUED.
日本人での発現はなかった。
相互参照：M16-048試験 CSR Table 14.3 2.17.23

表 2.7.4.7-37. 全試験期間中（投与 16 週時データカットオフまで）の重篤な有害事象の一覧表（Safety_DB_M 集団）：M16-045 試験

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:68.0 KG

PRE TO -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 study drug and no more than 30 days after the last dose of study drug. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:68.0 KG								
	DB	1 TO 32	31	31	R: BILATERAL INVASIVE DUCTAL CARSINOMA OF BREAST S: 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） P: 浸潤性乳管癌 L: Invasive ductal breast carcinoma	O: Yes	T: Grade 4 R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: DISCONTINUED STUDY	S: Yes, Hospitalization or prolonged hospitalization, Persistent or significant disability/incapacity, Important medical or surgical intervention, Life threatening O: MAYBE INHERITED OR THE USAGE OF IMMUNSUPRESSIVE DRUGS BEFORE A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:68.0 KG

FU 33 TO

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:65.0 KG

PRE TO -1

DB 1 TO 115

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:65.0 KG								
	BE	116 TO	70	185	R: SCIATICA S: 神経系障害 P: 坐骨神経痛 L: Sciatica		T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: DISCAL HERNIA L5S1 A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:65.0 KG								
	BE	116 TO	95	210	R: LOW BACK PAIN, SCAR FROM THE SURGERY OF INFLAMMATORY DISC HERNIATION. S: 傷害、中毒および処置合併症 P: 瘢痕 L: Surgical scar		T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: RECENT OPERATION OF A HERNIATED DISC A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:65.0 KG								
	BE	116 TO	95	210	R: LOW BACK PAIN, SCAR FROM THE SURGERY OF INFLAMMATORY DISC HERNIATION. S: 筋骨格系および結合組織障害 P: 背部痛 L: Low back pain		T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: RECENT OPERATION OF A HERNIATED DISC A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:65.0 KG								
	BE	116 TO	95	210	R: LOW BACK PAIN, SCAR FROM THE SURGERY OF INFLAMMATORY DISC HERNIATION. S: 筋骨格系および結合組織障害 P: 椎間板突出 L: Intervertebral disc herniation		T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: RECENT OPERATION OF A HERNIATED DISC A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:65.0 KG								
	BE	116 TO	151	266	R: SPONDYLODISCITIS S: 感染症および寄生虫症 P: 椎間板炎 L: Spondylodiscitis	I: Yes	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:94.0 KG							
	PRE	TO -1						
	DB	1 TO 112	43	43	R: THORACIC PAIN S: 一般・全身障害および投与部位の状態 P: 胸痛 L: Thoracic pain	E: 59 L: 17 Days	T: Grade 2 R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: NONE	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY
	BE	113 TO 225						
	FU	226 TO						

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:75.0 KG

PRE TO -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 study drug and no more than 30 days after the last dose of study drug. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:75.0 KG								
	DB	1 TO 112	30	30	R: FOOT BREAK S: 傷害、中毒および処置合併症 P: 足骨折 L: Foot fracture	E: 37 L: 8 Days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, FOOT SURGERY)	S: Yes, Hospitalization or prolonged hospitalization O: PATIENT FELT DOWN WHILE HE WAS RIDING A BIKE, AND BROKE HIS FOOT A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:75.0 KG								
	BE	113 TO	112	224	R: CHRONIC OBSTRUCTIVE PULMONARY DISEASE EXACERBATION S: 呼吸器、胸郭および縦隔障害 P: 慢性閉塞性肺疾患 L: COPD exacerbation	E: 239 L: 16 Days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: COPD MEDICAL HISTORY A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch	---- Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:84.1 KG								
	PRE	TO -1						
	DB	1 TO 112						
	BE	113 TO	251	363	R: SEPSIS WITHOUT ACUTE END ORGAN DYSFUNCTION. S: 感染症および寄生虫症 P: 敗血症 L: Sepsis	E: 373 L: 11 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: FURUNCULOSIS A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:73.0 KG

PRE TO -1

DB 1 TO 140

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 15 mg QD								
[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:73.0 KG								
	BE	141 TO 150	9	149	R: ISCHEMIC STROKE S: 神経系障害 P: 虚血性脳卒中 L: Ischemic stroke	E: 163 L: 15 Days	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: DISCONTINUED STUDY	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening O: SMALL VESSEL DISEASE RELATED TO UNCONTROLLED HYPERTENSION A: NO REASONABLE POSSIBILITY
	FU	151 TO						

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 15 mg QD								
[redacted] AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:78.9 KG								
	PRE	TO -1						
	DB	1 TO 112						
	BE	113 TO 169						
	FU	170 TO	13	182	R: ELECTIVE ABORTION S: 外科および内科処置 P: 人工流産 L: Elective abortion	E: 182 L: 1 Day	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Important medical or surgical intervention O: PREGNANCY A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:108.0 KG

PRE TO -1

DB 1 TO 114

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:108.0 KG								
	BE	115 TO	80	194	R: ATRIAL FIBRILLATION S: 心臓障害 P: 心房細動 L: Atrial fibrillation	E: 290 L: 97 Days I: Yes	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, CARDIOVERSION ON 18OCT2019 STRESS TEST PERFORMED ON 25/SEP/2019 RESTING ECG; ATRIAL FIBRILATION WITH NON SPECIFIC ST-T CHANGES. STRESS HAD NORMAL ST RESPONSE WITH VPB'S. CHEST PAIN	S: Yes, Hospitalization or prolonged hospitalization O: CARDIAC RISK FACTORS, HYPERTENSION, OBESITY A: NO REASONABLE POSSIBILITY E: No

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:108.0 KG							
	BE	115 TO	80	194	R: CHOLECYSTITIS S: 肝胆道系障害 P: 胆嚢炎 L: Cholecystitis	E: 198 L: 5 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: SURGICAL INTERVENTION	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening O: GALL STONES E: No

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:108.0 KG								
	BE	115 TO	80	194	R: PANCREATITIS S: 胃腸障害 P: 膵炎 L: Pancreatitis	E: 198 L: 5 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: SURGICAL INTERVENTION	S: Yes, Hospitalization or prolonged hospitalization O: CHOLELITHIASIS A: NO REASONABLE POSSIBILITY E: No

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:57.0 KG

PRE TO -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 study drug and no more than 30 days after the last dose of study drug. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 15 mg QD								
[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:57.0 KG								
	DB	1 TO 113	50	50	R: SEVERED TENDON ON BIG TOE RIGHT FOOT S: 傷害、中毒および処置合併症 P: 腱断裂 L: Severed tendon	E: 85 L: 36 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Important medical or surgical intervention O: A GLASS OBJECT FELL ON THE FOOT. THERE WAS A WOUND AND THE TENDON CUT. A: NO REASONABLE POSSIBILITY
	BE	114 TO						

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:77.3 KG

PRE TO -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 study drug and no more than 30 days after the last dose of study drug. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:77.3 KG								
	DB	1 TO 111	8	8	R: FLARE OF RIGHT HIP LABRAL TEAR S: 傷害、中毒および処置合併症 P: 軟骨損傷 L: Acetabular labral tear	E: 24 L: 17 Days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: SPORTS INJURY FROM CYCLING AND MARATHON RUNNING. ORIGINAL INJURY OCCURRED IN 20[redacted]. FLARE OF LABRAL TEAR OCCURRED ON [redacted] 20[redacted] AS DOCUMENTED. THIS SPORTS INJURY CAUSED THE LABRAL TEAR A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:77.3 KG

BE 112 TO

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:78.5 KG								
	PRE	TO -1						
	DB	1 TO 64	50	50	R: ASTHMA EXACERBATION WITH COFOUNDING FACTORS S: 呼吸器、胸郭および縦隔障害 P: 喘息 L: Exacerbation of asthma	E: 56 L: 7 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: ASTHMA A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:78.5 KG

FU 65 TO

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch	---- Interval	RX Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD									
[redacted] AGE:3[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:82.0 KG									
	PRE	TO -1							
	DB	1 TO 30	27	27		R: RETROPHARYNGEAL ABSCESS S: 感染症および寄生虫症 P: 咽頭膿瘍 L: Retropharyngeal abscess	E: 64 L: 38 Days	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY
	FU	31 TO							

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:56.0 KG

PRE TO -1

DB 1 TO 113

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:2[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:56.0 KG								
	BE	114 TO 141	6	119	R: GALLBLADDER POLYPS S: 肝胆道系障害 P: 胆嚢ポリープ L: Gallbladder polyp	E: 156 L: 38 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: INTRAOPERATIVE PATHOLOGICAL DIAGNOSIS SUGGESTS CHRONIC CHOLECYSTITIS A: NO REASONABLE POSSIBILITY
	FU	142 TO						

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:88.5 KG

PRE TO -1

DB 1 TO 112

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 15 mg QD								
[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:88.5 KG								
	BE	113 TO	61	173	R: APPENDICITIS S: 感染症および寄生虫症 P: 虫垂炎 L: Appendicitis	E: 208 L: 36 Days	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, APPENDECTOMY ON 01NOV2019)	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:4[redacted] SEX:MALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:87.3 KG

PRE TO -1

DB 1 TO 118

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted] AGE:4[redacted] SEX:MALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:87.3 KG								
	BE	119 TO	250	368	R: VIRAL PNEUMONIA S: 感染症および寄生虫症 P: ウイルス性肺炎 L: Viral pneumonia	E: 400 L: 33 Days	T: Grade 4 R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening O: COVID-19 A: NO REASONABLE POSSIBILITY E: Yes

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 15 mg QD								
[redacted] AGE:2[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:72.3 KG								
	PRE	TO -1						
	DB	1 TO 111	13	13	R: ANAPHYLACTIC SHOCK (TO PINE NUTS) S: 免疫系障害 P: アナフィラキシーショック L: Anaphylactic shock due to tree nuts and seeds	E: 13 L: 1 Day	T: Grade 4 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Life threatening O: ALLERGY TO NUTS A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:72.3 KG

BE 112 TO

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 30 mg QD								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:66.4 KG								
	PRE	TO -1						
	DB	1 TO 112						
	BE	113 TO	64	176	R: PYELONEPHRITIS S: 感染症および寄生虫症 P: 腎盂腎炎 L: Pyelonephritis	E: 181 L: 6 Days	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization A: REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted]	AGE:2[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:83.1 KG							
	PRE	TO -1						
	DB	1 TO 116						
	BE	117 TO	104	220	R: GASTROENTERITIS S: 感染症および寄生虫症 P: 胃腸炎 L: Gastroenteritis	E: 228 L: 9 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: FOOD POISONING A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:FEMALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:95.0 KG

PRE TO -1

DB 1 TO 112

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted] AGE:2[redacted] SEX:FEMALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:95.0 KG								
	BE	113 TO	17	129	R: MANIC EPISODE S: 精神障害 P: 躁病 L: Manic episode	E: 135 L: 7 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: SUBJECT EXPERIENCED INSOMNIA THAT RESULTED IN A MANIC EPISODE WHICH REQUIRED A HOSPITALIZATION A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:MALE RACE:ASIAN WEIGHT:47.5 KG

PRE TO -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 study drug and no more than 30 days after the last dose of study drug. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:2[redacted] SEX:MALE RACE:ASIAN WEIGHT:47.5 KG								
	DB	1 TO 63	40	40	R: CONTACT DERMATITIS S: 皮膚および皮下組織障害 P: 接触皮膚炎 L: Contact dermatitis	E: 57 L: 18 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: AN ALLERGIC REACTION BECAUSE OF UNDERLYING ATOPIC DERMATITIS FACTOR A: NO REASONABLE POSSIBILITY
	FU	64 TO						

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:108.9 KG								
	PRE	TO -1						
	DB	1 TO 113						
	BE	114 TO	62	175 &	R: PNEUMONIA S: 感染症および寄生虫症 P: 肺炎 L: Pneumonia	E: 231 L: 57 Days	T: Grade 2 R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Important medical or surgical intervention A: NO REASONABLE POSSIBILITY E: No

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
& Date is estimated.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 30 mg QD								
[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:63.0 KG								
	PRE	TO -1						
	DB	1 TO 112						
	BE	113 TO 432	119	231	R: FULL THICKNESS BURN BSA 7% S: 傷害、中毒および処置合併症 P: 第3度熱傷 L: Burns third degree	E: 246 L: 16 Days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Important medical or surgical intervention O: ACCIDENTAL BURN IN SAUNA A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:63.0 KG

FU 433 TO

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 30 mg QD								
[redacted]	AGE:5[redacted] SEX:MALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:110.2 KG							
	PRE	TO -1						
	DB	1 TO 112						
	BE	113 TO	180	292	R: COVID-19 INFECTION S: 感染症および寄生虫症 P: コロナウイルス感染 L: Coronavirus infection	E: 328 L: 37 Days	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 30 mg QD								
[redacted] AGE:5[redacted] SEX:MALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:110.2 KG								
	BE	113 TO	184	296	R: BACTERIAL PNEUMONIA S: 感染症および寄生虫症 P: 細菌性肺炎 L: Pneumonia bacterial	E: 299 L: 4 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONTINUE HOSPITALIZATION COURSE	S: Yes, Hospitalization or prolonged hospitalization O: SOCONDARY INFECTION DUE TO COVID 19 A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch	---- Interval	RX Day of Onset Day	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:60.6 KG								
	PRE	TO -1						
	DB	1 TO 117						
	BE	118 TO 258	54	171	R: EXACERBATION OF ATOPIC DERMATITIS S: 皮膚および皮下組織障害 P: アトピー性皮膚炎 L: Dermatitis atopic aggravated	E: 232 L: 62 Days	T: Grade 4 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: PRE-EXISTING ATOPIC DERMATITIS A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:60.6 KG

FU 259 TO

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:78.5 KG

PRE TO -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 study drug and no more than 30 days after the last dose of study drug. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 30 mg QD								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:78.5 KG								
	DB	1 TO 120	68	68	R: HOSPITALISATION DUE TO EXACERBATION OF ATOPIC DERMATITIS S: 皮膚および皮下組織障害 P: アトピー性皮膚炎 L: Dermatitis atopic aggravated	E: 75 L: 8 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: EXACCERBATION OF PRE-EXISTING SEVERE ATOPIC DERMATITIS A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 30 mg QD								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:78.5 KG								
	BE	121 TO 243	122	242	R: MRSA SEPSIS (WITH POSITIVE BLOOD AND URINE CULTURES) S: 感染症および寄生虫症 P: ブドウ球菌性敗血症 L: Sepsis MRSA	O: Yes	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening A: REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 30 mg QD								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:78.5 KG								
	BE	121 TO 243	122	242	R: MRSA SEPSIS (WITH POSITIVE BLOOD AND URINE CULTURES) S: 臨床検査 P: 血液培養陽性 L: Blood culture positive	O: Yes	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening A: REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 30 mg QD								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:78.5 KG								
	BE	121 TO 243	122	242	R: MRSA SEPSIS (WITH POSITIVE BLOOD AND URINE CULTURES) S: 臨床検査 P: 尿培養陽性 L: Urine culture positive	O: Yes	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening A: REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 30 mg QD								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:78.5 KG								
	BE	121 TO 243	122	242	R: MULTIFOCAL OSTEOMYELITIS S: 感染症および寄生虫症 P: 骨髄炎 L: Osteomyelitis	O: Yes	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, SURGICAL DRAINAGE OF FLUID RIGHT HIP)	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: IMPACT INJURY TO RIGHT HIP FOLLOWING A FALL A: REASONABLE POSSIBILITY
	FU	244 TO						

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:76.3 KG								
	PRE	TO -1						
	DB	1 TO 112	14	14	R: ANAPHYLACTIC REACTION TO NUTS S: 免疫系障害 P: アナフィラキシー反応 L: Anaphylactic reaction to food	E: 14 L: 1 Day	T: Grade 4 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Life threatening O: PATIENT ACCIDENTALLY ATE PESTO SAUCE A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:76.3 KG

BE 113 TO

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:79.0 KG

PRE TO -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 study drug and no more than 30 days after the last dose of study drug. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:79.0 KG								
	DB	1 TO 112	112	112	R: RIGHT SIDED PNEUMONIA CAUSED BY STAPHYLOCOCCUS AUREUS S: 感染症および寄生虫症 P: ブドウ球菌性肺炎 L: Staphylococcus aureus pneumonia	E: 142 L: 31 Days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: STAPHYLOCOCCUS AUREUS A: NO REASONABLE POSSIBILITY
	BE	113 TO						

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:51.0 KG

PRE TO -1

DB 1 TO 112

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 30 mg QD								
[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:51.0 KG								
	BE	113 TO	13	125	R: ALLERGIC REACTION TO DAIRY S: 免疫系障害 P: 乳アレルギー L: Milk allergy	E: 128 L: 4 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening O: NEW FOOD ALLERGY A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:75.9 KG

PRE TO -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 study drug and no more than 30 days after the last dose of study drug. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:75.9 KG								
	DB	1 TO 48	36	36	R: GASTRIC TUMOR (MALIGNANT) S: 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） P: 胃癌 L: Malignant neoplasm of stomach	O: Yes	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: Yes, Hospitalization or prolonged hospitalization O: REFLUX ESOPHAGITIS WITH MUCOSAL PROLIFERATION AND MUCOSAL HEMORRHAGES AND EROSIVE PANGASTRITIS WITH ULCEROUS GASTRIC ULCER ARE CRUCIAL F A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:75.9 KG

FU 49 TO

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: Placebo

[redacted] AGE:5[redacted] SEX:MALE RACE:ASIAN WEIGHT:63.2 KG

PRE TO -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 study drug and no more than 30 days after the last dose of study drug. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo								
[redacted] AGE:5[redacted] SEX:MALE RACE:ASIAN WEIGHT:63.2 KG								
	DB	1 TO 7	1	1	R: WORSENING OF ATOPIC DERMATITIS S: 皮膚および皮下組織障害 P: アトピー性皮膚炎 L: Dermatitis atopic aggravated	E: 17 L: 17 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: PI THINK THIS EVENT HAS BEEN CAUSED BY STOPPING OF APPLYING TOPICAL STEROID TREATMENT RATHER THAN ADMINISTRATION OF THE INVESTIGATIONAL DRUG. A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: Placebo

[redacted] AGE:5[redacted] SEX:MALE RACE:ASIAN WEIGHT:63.2 KG

FU 8 TO

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:MALE RACE:ASIAN WEIGHT:67.4 KG

PRE TO -1

DB 1 TO 112

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted] AGE:3[redacted] SEX:MALE RACE:ASIAN WEIGHT:67.4 KG								
	BE	113 TO	37	149	R: RETINAL DETACHMENT S: 眼障害 P: 網膜剥離 L: Retinal detachment	E: 169 L: 21 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: RETINAL DETACHMENT IS ONE OF THE OCULAR COMPLICATIONS OF AD. THE PATIENT HAS SEVERE AD, ESPECIALLY IN HIS FACE. HE OFTEN RUBS HIS EYES. SO HIS RETINAL DETACHMENT IS POSSIBLY DUE TO EYE RUBBING. A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:FEMALE RACE:MULTIPLE WEIGHT:54.3 KG

PRE	TO -1
DB	1 TO 112
BE	113 TO 135

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted] AGE:5[redacted] SEX:FEMALE RACE:MULTIPLE WEIGHT:54.3 KG								
	FU	136 TO	5	140	R: TOXIC EPIDERMAL NECROLYSIS S: 皮膚および皮下組織障害 P: 中毒性表皮壊死融解症 L: Toxic epidermal necrolysis	E: 149 L: 10 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: ANTIBIOTIC ALLERGY (CEFADROXIL) A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted]	AGE:2[redacted] SEX:MALE RACE:MULTIPLE WEIGHT:74.5 KG							
	PRE	TO -1						
	DB	1 TO 105	96	96	R: ACUTE APPENDICITIS S: 感染症および寄生虫症 P: 虫垂炎 L: Acute appendicitis	E: 100 L: 5 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: APPENDIX IMFLAMMATION A: NO REASONABLE POSSIBILITY
	BE	106 TO						

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted] AGE:3[redacted] SEX:MALE RACE:ASIAN WEIGHT:76.1 KG								
	PRE	TO -1						
	DB	1 TO 112	42	42	R: ALLERGIC REACTION TO PINE NUTS S: 免疫系障害 P: 食物アレルギー L: Allergy to nuts	E: 42 L: 1 Day	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Important medical or surgical intervention O: ALLERGIC REACTION TO PINE NUTS KNOWN MEDICAL HISTORY A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:MALE RACE:ASIAN WEIGHT:76.1 KG

BE 113 TO

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:110.0 KG

PRE TO -1

DB 1 TO 112

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:110.0 KG								
	BE	113 TO 199	86	198	R: MUSCULAR PAIN UPPER LEG LEFT - CAUSE UNKNOWN S: 筋骨格系および結合組織障害 P: 筋肉痛 L: Myalgia of lower extremities	E: 259 L: 62 Days	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, CURATIVE EURYTHMIE, RHYTMIC MASSAGE, PHYSICAL THERAPY)	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY
	FU	200 TO						

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch	---- Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted]	AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:51.0 KG							
	PRE	TO -1						
	DB	1 TO 111						
	BE	112 TO 183	72	183	R: COMMUNITY-ACQUIRED BILATERAL PNEUMONIA S: 感染症および寄生虫症 P: 肺炎 L: Community acquired pneumonia	O: Yes	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: Yes, Hospitalization or prolonged hospitalization A: REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:51.0 KG

FU 184 TO

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:4[redacted] SEX:FEMALE RACE:MULTIPLE WEIGHT:67.0 KG

PRE TO -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 study drug and no more than 30 days after the last dose of study drug. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 15 mg QD								
[redacted] AGE:4[redacted] SEX:FEMALE RACE:MULTIPLE WEIGHT:67.0 KG								
	DB	1 TO 129	53	53	R: WORSENING ALLERGIC RHINITIS S: 呼吸器、胸郭および縦隔障害 P: アレルギー性鼻炎 L: Allergic rhinitis	E: 54 L: 2 Days	T: Grade 1 R: REASONABLE POSSIBILITY A: MULTIPLE (DRUG INTERRUPTED, - BLOOD EXAMS - QUANTIFERON TEST - CHEST X RAY - SPECIALIST CONSULTING -SPUTUM CULTURE) O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: HOSPITALIZATION FOR EVALUATION OF SUSPECT OF TB A: NO REASONABLE POSSIBILITY
	BE	130 TO						

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:72.0 KG								
	PRE	TO -1						
	DB	1 TO 111						
	BE	112 TO	10	121	R: PNEUMONIA S: 感染症および寄生虫症 P: 肺炎 L: Pneumonia	E: 138 L: 18 Days	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: LOWER RESPIRATORY TRACT INFECTION A: REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo								
[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:53.3 KG								
	PRE	TO -1						
	DB	1 TO 14	14	14	R: ERYTHRODERMA S: 皮膚および皮下組織障害 P: 全身性剥脱性皮膚炎 L: Erythroderma	E: 18 L: 5 Days	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY
	FU	15 TO						

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted]	AGE:3[redacted] SEX:MALE RACE:ASIAN WEIGHT:87.7 KG							
	PRE	TO -1						
	DB	1 TO 113	9	9	R: ALLERGIC REACTION TO ALLERGEN INJECTED BY FAMILY PHYSICIAN S: 免疫系障害 P: 過敏症 L: Allergic reaction	E: 9 L: 1 Day I: Yes	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Life threatening O: REACTION TO ALLERGEN GIVEN BY HIS ALLERGY SPECIALIST A: NO REASONABLE POSSIBILITY
	BE	114 TO						

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:72.6 KG

PRE TO -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 study drug and no more than 30 days after the last dose of study drug. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 30 mg QD								
[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:72.6 KG								
	DB	1 TO 112	108	108	R: SUBMENTAL/MIDLINE SUBMANDIBULAR SWELLING (LYMPH NODE SWELLING) S: 血液およびリンパ系障害 P: リンパ節症 L: Submandibular lymphadenopathy	E: 109 L: 2 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, ULTRASOUND OF NECK AND FLEXIBLE ENDOSCOPY)	S: Yes, Hospitalization or prolonged hospitalization O: ? CELLULITIS SECONDARY TO ECZEMA WITH LYMPHADENTITIS A: NO REASONABLE POSSIBILITY
	BE	113 TO						

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo								
[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:70.0 KG								
	PRE	TO -1						
	DB	1 TO 28	20	20	R: WORSENING OF ATOPIC DERMATITIS S: 皮膚および皮下組織障害 P: アトピー性皮膚炎 L: Dermatitis atopic aggravated	O: Yes	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: Yes, Hospitalization or prolonged hospitalization O: ATOPIC DERMATITIS A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: Placebo

[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:70.0 KG

FU 29 TO

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted]	AGE:1[redacted] SEX:FEMALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:76.2 KG							
	PRE	TO -1						
	DB	1 TO 112	82	82	R: WORSENING IMPETIGO AROUND LIPS S: 感染症および寄生虫症 P: 膿痂疹 L: Impetigo	E: 155 L: 74 Days	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY
	BE	113 TO 138						
	FU	139 TO						

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:3[redacted] SEX:MALE RACE:ASIAN WEIGHT:76.0 KG								
	PRE	TO -1						
	DB	1 TO 114						
	BE	115 TO	43	157	R: PNEUMONIA S: 感染症および寄生虫症 P: 肺炎 L: Pneumonia	E: 167 L: 11 Days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: ASTHMA A: REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
被験者番号17071003，17051002及び17051003は日本人であった。
相互参照：M16-045 試験 CSR W16 Table 14.3　2.24.1

表 2.7.4.7-38. 全試験期間中（投与 52 週時データカットオフまで）の重篤な有害事象の一覧表（ALL UPA_M 集団）：M16-045 試験

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 15 mg QD								
[redacted] AGE:4[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:55.6 KG								
	PRE	TO -1						
	DB	1 TO 113						
	BE	114 TO 535	407	520	R: BREAST CANCER(LEFT) S: 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） P: 乳癌 L: Breast cancer		T: Grade 4 R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: LEFT MASTECTOMY,LYMPH NODE BIOPSY.	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 15 mg QD								
[redacted] AGE:4[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:55.6 KG								
	FU	536 TO	15	550	R: CANCER OF TRANSVERSE COLON S: 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） P: 結腸癌 L: Cancer of transverse colon		T: Grade 4 R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: SCHEDULED TO BE ADMITTED TO ANOTHER HOSPITAL FOR TREATMENT ON [redacted]20[redacted], WITH SURGERY SCHEDULED ON [redacted]20[redacted].	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:68.0 KG

PRE TO -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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:68.0 KG								
	DB	1 TO 32	25	25	R: BILATERAL INVASIVE DUCTAL CARSINOMA OF BREAST S: 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） P: 浸潤性乳管癌 L: Invasive ductal breast carcinoma	O: Yes	T: Grade 4 R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: DISCONTINUED STUDY	S: Yes, Hospitalization or prolonged hospitalization, Persistent or significant disability/incapacity, Important medical or surgical intervention, Life threatening O: MAYBE INHERITED OR THE USAGE OF IMMUNSUPRESSIVE DRUGS BEFORE A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:68.0 KG

FU 33 TO

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:65.0 KG

PRE TO -1

DB 1 TO 115

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:65.0 KG								
	BE	116 TO	70	185	R: SCIATICA S: 神経系障害 P: 坐骨神経痛 L: Sciatica		T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: DISCAL HERNIA L5S1 A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:65.0 KG								
	BE	116 TO	95	210	R: LOW BACK PAIN, SCAR FROM THE SURGERY OF INFLAMMATORY DISC HERNIATION. S: 傷害、中毒および処置合併症 P: 瘢痕 L: Surgical scar		T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: RECENT OPERATION OF A HERNIATED DISC A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:65.0 KG								
	BE	116 TO	95	210	R: LOW BACK PAIN, SCAR FROM THE SURGERY OF INFLAMMATORY DISC HERNIATION. S: 筋骨格系および結合組織障害 P: 背部痛 L: Low back pain		T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: RECENT OPERATION OF A HERNIATED DISC A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:65.0 KG								
	BE	116 TO	95	210	R: LOW BACK PAIN, SCAR FROM THE SURGERY OF INFLAMMATORY DISC HERNIATION. S: 筋骨格系および結合組織障害 P: 椎間板突出 L: Intervertebral disc herniation		T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: RECENT OPERATION OF A HERNIATED DISC A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:65.0 KG								
	BE	116 TO	151	266	R: SPONDYLODISCITIS S: 感染症および寄生虫症 P: 椎間板炎 L: Spondylodiscitis	I: Yes	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:94.0 KG							
	PRE	TO -1						
	DB	1 TO 112	43	43	R: THORACIC PAIN S: 一般・全身障害および投与部位の状態 P: 胸痛 L: Thoracic pain	E: 59 L: 17 Days	T: Grade 2 R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: NONE	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY
	BE	113 TO 225						
	FU	226 TO						

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted]	AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:64.0 KG							
	PRE	TO -1						
	DB	1 TO 111						
	BE	112 TO 229	76	187	R: SUICIDAL IDEATION S: 精神障害 P: 自殺念慮 L: Suicidal ideation	E: 222 L: 36 Days	T: Grade 3 R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: DEPRESSIVE SYNDROME A: NO REASONABLE POSSIBILITY E: No
	FU	230 TO						

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued. s

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:75.0 KG

PRE TO -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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:75.0 KG								
	DB	1 TO 112	30	30	R: FOOT BREAK S: 傷害、中毒および処置合併症 P: 足骨折 L: Foot fracture	E: 37 L: 8 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, FOOT SURGERY)	S: Yes, Hospitalization or prolonged hospitalization O: PATIENT FELT DOWN WHILE HE WAS RIDING A BIKE, AND BROKE HIS FOOT A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:75.0 KG								
	BE	113 TO	112	224	R: CHRONIC OBSTRUCTIVE PULMONARY DISEASE EXACERBATION S: 呼吸器、胸郭および縦隔障害 P: 慢性閉塞性肺疾患 L: COPD exacerbation	E: 239 L: 16 Days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: COPD MEDICAL HISTORY A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:75.0 KG								
	BE	113 TO	129	241	R: DISCAL HERNIA S: 筋骨格系および結合組織障害 P: 椎間板突出 L: Herniated disc	E: 332 L: 92 Days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, SURGERY)	S: Yes, Hospitalization or prolonged hospitalization O: UNKNOWN A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:75.0 KG								
	BE	113 TO	306	418	R: MUSCULOSKELETAL CHEST PAIN S: 筋骨格系および結合組織障害 P: 筋骨格系胸痛 L: Musculoskeletal chest pain	E: 419 L: 2 Days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: UNKNOWN A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:75.0 KG								
	BE	113 TO	444	556	R: ATYPICAL PNEUMONIA S: 感染症および寄生虫症 P: 異型肺炎 L: Atypical pneumonia		T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: UNKNOWN A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch	---- Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:84.1 KG								
	PRE	TO -1						
	DB	1 TO 112						
	BE	113 TO	251	363	R: SEPSIS WITHOUT ACUTE END ORGAN DYSFUNCTION. S: 感染症および寄生虫症 P: 敗血症 L: Sepsis	E: 373 L: 11 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: FURUNCULOSIS A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:73.0 KG

PRE TO -1

DB 1 TO 140

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch	Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 15 mg QD									
[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:73.0 KG									
	BE	141 TO 150	9	149	R: ISCHEMIC STROKE S: 神経系障害 P: 虚血性脳卒中 L: Ischemic stroke	E: 163 L: 15 Days	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: DISCONTINUED STUDY	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening O: SMALL VESSEL DISEASE RELATED TO UNCONTROLLED HYPERTENSION A: NO REASONABLE POSSIBILITY
	FU	151 TO						

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 15 mg QD								
[redacted] AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:78.9 KG								
	PRE	TO -1						
	DB	1 TO 112						
	BE	113 TO 169						
	FU	170 TO	13	182	R: ELECTIVE ABORTION S: 外科および内科処置 P: 人工流産 L: Elective abortion	E: 182 L: 1 Day	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Important medical or surgical intervention O: PREGNANCY A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:86.2 KG

PRE TO -1

DB 1 TO 113

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:86.2 KG								
	BE	114 TO	234	347	R: STAPHYLOCOCCUS AUREUS SEPSIS S: 感染症および寄生虫症 P: ブドウ球菌性敗血症 L: Staphylococcus aureus septicemia	E: 380 L: 34 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: IT IS BELIEVED THE SUBJECT MAY HAVE BEEN INFECTED BY GYM EQUIPMENT CONTACT IN OPEN SORE. OTHERWISE UNKNOWN. A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:108.0 KG

PRE TO -1

DB 1 TO 114

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:108.0 KG								
	BE	115 TO	80	194	R: ATRIAL FIBRILLATION S: 心臓障害 P: 心房細動 L: Atrial fibrillation	E: 290 L: 97 Days I: Yes	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, CARDIOVERSION ON [redacted]20[redacted] STRESS TEST PERFORMED ON [redacted]/[redacted]/20[redacted] RESTING ECG; ATRIAL FIBRILATION WITH NON SPECIFIC ST-T CHANGES. STRESS HAD NORMAL ST RESPONSE WITH VPB'S. CHEST PAIN	S: Yes, Hospitalization or prolonged hospitalization O: CARDIAC RISK FACTORS, HYPERTENSION, OBESITY A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted]	AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:108.0 KG							
	BE	115 TO	80	194	R: CHOLECYSTITIS S: 肝胆道系障害 P: 胆嚢炎 L: Cholecystitis	E: 198 L: 5 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: SURGICAL INTERVENTION	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening O: GALL STONES E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:108.0 KG								
	BE	115 TO	80	194	R: PANCREATITIS S: 胃腸障害 P: 膵炎 L: Pancreatitis	E: 198 L: 5 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: SURGICAL INTERVENTION	S: Yes, Hospitalization or prolonged hospitalization O: CHOLELITHIASIS A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:84.0 KG

PRE TO -1

DB 1 TO 112

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:84.0 KG								
	BE	113 TO	531	643	R: CHOLESTEATOMA OF MIDDLE EAR RIGHT S: 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） P: 真珠腫 L: Cholesteatoma of middle ear	E: 644 L: 2 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: OTITIS MEDIA A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:77.3 KG

PRE TO -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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:77.3 KG								
	DB	1 TO 111	8	8	R: FLARE OF RIGHT HIP LABRAL TEAR S: 傷害、中毒および処置合併症 P: 軟骨損傷 L: Acetabular labral tear	E: 24 L: 17 Days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: SPORTS INJURY FROM CYCLING AND MARATHON RUNNING. ORIGINAL INJURY OCCURRED IN 20[redacted]. FLARE OF LABRAL TEAR OCCURRED ON [redacted] 20[redacted] AS DOCUMENTED. THIS SPORTS INJURY CAUSED THE LABRAL TEAR A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:77.3 KG

BE 112 TO

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:70.4 KG

PRE TO -1

DB 1 TO 117

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted] AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:70.4 KG								
	BE	118 TO	44	161	R: LEFT BREAST ABSCESS S: 感染症および寄生虫症 P: 乳房膿瘍 L: Breast abscess	E: 196 L: 36 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Important medical or surgical intervention O: THE SUBJECT HAD A BREAST LUMP WHICH WAS IDENTIFIED AS AN INFECTION UNDER BIOPSY. THE BIOPSY SITE CAUSED THE SPREAD OF THE INFECTION AND THE ABSCESS DEVELOPED A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:78.5 KG								
	PRE	TO -1						
	DB	1 TO 64	50	50	R: ASTHMA EXACERBATION WITH COFOUNDING FACTORS S: 呼吸器、胸郭および縦隔障害 P: 喘息 L: Exacerbation of asthma	E: 56 L: 7 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: ASTHMA A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:78.5 KG

FU 65 TO

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:3[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:82.0 KG								
	PRE	TO -1						
	DB	1 TO 30	27	27	R: RETROPHARYNGEAL ABSCESS S: 感染症および寄生虫症 P: 咽頭膿瘍 L: Retropharyngeal abscess	E: 64 L: 38 Days	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY
	FU	31 TO						

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:56.0 KG

PRE TO -1

DB 1 TO 113

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:2[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:56.0 KG								
	BE	114 TO 141	6	119	R: GALLBLADDER POLYPS S: 肝胆道系障害 P: 胆嚢ポリープ L: Gallbladder polyp	E: 156 L: 38 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: INTRAOPERATIVE PATHOLOGICAL DIAGNOSIS SUGGESTS CHRONIC CHOLECYSTITIS A: NO REASONABLE POSSIBILITY
	FU	142 TO						

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:79.4 KG

PRE TO -1

DB 1 TO 107

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 15 mg QD								
[redacted] AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:79.4 KG								
	BE	108 TO	580	687	R: SURGICAL SITE INFECTION, RIGHT ANKLE S: 感染症および寄生虫症 P: 術後創感染 L: Surgical site infection		T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: INFECTION OF INTERNAL SUTURE FROM PRIOR RIGHT ACHILLES TENDON SURGERY. A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 15 mg QD								
[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:88.5 KG								
	PRE	TO -1						
	DB	1 TO 112						
	BE	113 TO	61	173	R: APPENDICITIS S: 感染症および寄生虫症 P: 虫垂炎 L: Appendicitis	E: 208 L: 36 Days	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, APPENDECTOMY ON 01NOV2019)	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:4[redacted] SEX:MALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:87.3 KG

PRE TO -1

DB 1 TO 118

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted] AGE:4[redacted] SEX:MALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:87.3 KG								
	BE	119 TO	247	365	R: COVID-19 INFECTION S: 感染症および寄生虫症 P: コロナウイルス感染 L: Coronavirus infection	E: 400 L: 36 Days	T: Grade 4 R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening O: COVID-19 E: Yes

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 30 mg QD								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:66.4 KG								
	PRE	TO -1						
	DB	1 TO 112						
	BE	113 TO	64	176	R: PYELONEPHRITIS S: 感染症および寄生虫症 P: 腎盂腎炎 L: Pyelonephritis	E: 181 L: 6 Days	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization A: REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch	---- Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:2[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:83.1 KG								
	PRE	TO -1						
	DB	1 TO 116						
	BE	117 TO	104	220	R: GASTROENTERITIS S: 感染症および寄生虫症 P: 胃腸炎 L: Gastroenteritis	E: 228 L: 9 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: FOOD POISONING A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:FEMALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:95.0 KG

PRE TO -1

DB 1 TO 112

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted] AGE:2[redacted] SEX:FEMALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:95.0 KG								
	BE	113 TO	17	129	R: MANIC EPISODE S: 精神障害 P: 躁病 L: Manic episode	E: 135 L: 7 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: SUBJECT EXPERIENCED INSOMNIA THAT RESULTED IN A MANIC EPISODE WHICH REQUIRED A HOSPITALIZATION A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted] AGE:2[redacted] SEX:FEMALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:95.0 KG								
	BE	113 TO	109	221	R: MANIC EPISODE S: 精神障害 P: 躁病 L: Manic episode		T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: SUBJECT WAS HOSPITALIZED ON FOR A MEDICATION ADJUSTMENT DUE TO TRAZADONE INEFFECTIVELY MANAGING HER INSOMNIA A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:MALE RACE:ASIAN WEIGHT:47.5 KG

PRE TO -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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:2[redacted] SEX:MALE RACE:ASIAN WEIGHT:47.5 KG								
	DB	1 TO 63	40	40	R: CONTACT DERMATITIS S: 皮膚および皮下組織障害 P: 接触皮膚炎 L: Contact dermatitis	E: 57 L: 18 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: AN ALLERGIC REACTION BECAUSE OF UNDERLYING ATOPIC DERMATITIS FACTOR A: NO REASONABLE POSSIBILITY
	FU	64 TO						

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:107.5 KG

PRE TO -1

DB 1 TO 115

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 15 mg QD								
[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:107.5 KG								
	BE	116 TO 372	250	365	R: DEEP VEIN THROMBOSIS LEFT LOWER LEG S: 血管障害 P: 深部静脈血栓症 L: Deep vein thrombosis leg		T: Grade 4 R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, ULTRASOUND DONE ON [redacted] PATIENT REFERRED TO HEMATOLOGIST.)	S: Yes, Important medical or surgical intervention, Life threatening A: NO REASONABLE POSSIBILITY E: No
	FU	373 TO						

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:108.9 KG								
	PRE	TO -1						
	DB	1 TO 113						
	BE	114 TO	62	175 &	R: PNEUMONIA S: 感染症および寄生虫症 P: 肺炎 L: Pneumonia	E: 231 L: 57 Days	T: Grade 2 R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Important medical or surgical intervention A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
& Date is estimated.

Subject Number	------ Name	Epoch	---- Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 30 mg QD								
[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:63.0 KG								
	PRE	TO -1						
	DB	1 TO 112						
	BE	113 TO 432	119	231	R: FULL THICKNESS BURN BSA 7% S: 傷害、中毒および処置合併症 P: 第3度熱傷 L: Burns third degree	E: 246 L: 16 Days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Important medical or surgical intervention O: ACCIDENTAL BURN IN SAUNA A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 30 mg QD								
[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:63.0 KG								
	FU	433 TO	19	451	R: ELECTIVE TERMINATION OF PREGNANCY S: 外科および内科処置 P: 人工流産 L: Induced abortion	E: 453 L: 3 Days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Important medical or surgical intervention O: UNPLANNED PRENANCY A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 30 mg QD								
[redacted]	AGE:5[redacted] SEX:MALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:110.2 KG							
	PRE	TO -1						
	DB	1 TO 112						
	BE	113 TO	180	292	R: COVID-19 INFECTION S: 感染症および寄生虫症 P: コロナウイルス感染 L: Coronavirus infection	E: 328 L: 37 Days	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization E: Yes

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 30 mg QD								
[redacted] AGE:5[redacted] SEX:MALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:110.2 KG								
	BE	113 TO	184	296	R: BACTERIAL PNEUMONIA S: 感染症および寄生虫症 P: 細菌性肺炎 L: Pneumonia bacterial	E: 299 L: 4 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONTINUE HOSPITALIZATION COURSE	S: Yes, Hospitalization or prolonged hospitalization O: SOCONDARY INFECTION DUE TO COVID 19 A: NO REASONABLE POSSIBILITY E: Yes

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch	---- Interval	RX Day of Onset Day	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:60.6 KG								
	PRE	TO -1						
	DB	1 TO 117						
	BE	118 TO 258	54	171	R: EXACERBATION OF ATOPIC DERMATITIS S: 皮膚および皮下組織障害 P: アトピー性皮膚炎 L: Dermatitis atopic aggravated	E: 232 L: 62 Days	T: Grade 4 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: PRE-EXISTING ATOPIC DERMATITIS A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:60.6 KG

FU 259 TO

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:62.3 KG

PRE TO -1

DB 1 TO 113

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted] AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:62.3 KG								
	BE	114 TO 373	256	369	R: INFILTRATIVE TUBERCULOSIS S: 感染症および寄生虫症 P: 肺結核 L: Tuberculosis of lung, infiltrative	O: Yes	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, PHTHISIATRICIAN CONSULTATION SCHEDULED, DISCONTINUED STUDY)	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention A: REASONABLE POSSIBILITY
	FU	374 TO						

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:78.5 KG

PRE TO -1

DB 1 TO 120

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 30 mg QD								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:78.5 KG								
	BE	121 TO 243	122	242	R: MRSA SEPSIS S: 感染症および寄生虫症 P: ブドウ球菌性敗血症 L: Sepsis MRSA	O: Yes	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening A: REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 30 mg QD								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:78.5 KG								
	BE	121 TO 243	122	242	R: MULTIFOCAL OSTEOMYELITIS S: 感染症および寄生虫症 P: 骨髄炎 L: Osteomyelitis	O: Yes	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, SURGICAL DRAINAGE OF FLUID RIGHT HIP)	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: IMPACT INJURY TO RIGHT HIP FOLLOWING A FALL A: REASONABLE POSSIBILITY
	FU	244 TO						

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:75.5 KG

PRE TO -1

DB 1 TO 116

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 30 mg QD								
[redacted] AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:75.5 KG								
	BE	117 TO 309	137	253	R: NON-FUNCTIONING PITUITARY MACROADENOMA S: 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） P: 非分泌型下垂体腺腫 L: Non-secretory adenoma of pituitary	E: 316 L: 64 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, CONFIRMED VIA BRAIN MRI + ENDOCRINOLOGIST INVESTIGATIONS. SUBJECT HAD STEREOTACTIC ENDOSCOPIC ENDONASAL TRANSSPHENOIDAL RESECTION OF PITUITARY TUMOUR SURGERY ON [redacted] 20[redacted])	S: Yes, Important medical or surgical intervention O: RESECTION OF PITUITARY TUMOUR SURGERY A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:75.5 KG

FU 310 TO

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:76.3 KG								
	PRE	TO -1						
	DB	1 TO 112	14	14	R: ANAPHYLACTIC REACTION TO NUTS S: 免疫系障害 P: アナフィラキシー反応 L: Anaphylactic reaction to food	E: 14 L: 1 Day	T: Grade 4 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Life threatening O: PATIENT ACCIDENTALLY ATE PESTO SAUCE A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: QD

[redacted] AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:76.3 KG

BE 113 TO

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:6[redacted] SEX:MALE RACE:ASIAN WEIGHT:75.3 KG

PRE TO -1

DB 1 TO 112

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 30 mg QD								
[redacted] AGE:6[redacted] SEX:MALE RACE:ASIAN WEIGHT:75.3 KG								
	BE	113 TO	111	223	R: MACULAR HOLE IN RIGHT EYE S: 眼障害 P: 黄斑円孔 L: Macular hole	E: 286 L: 64 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: IT HAS BEEN CONFIRMED WITH THE PATIENT AGAIN THAT THE CAUSE CANNOT BE CONFIRMED A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:77.0 KG

PRE TO -1

DB 1 TO 112

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:77.0 KG								
	BE	113 TO	31	143 &	R: RECURRENT HEMORRHOIDS S: 胃腸障害 P: 痔核 L: Hemorrhoids	E: 374 L: 232 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, ELECTIVE SURGERY OF HEMORRHOIDS)	S: Yes, Hospitalization or prolonged hospitalization O: YES-FAMILY HISTORY OF HEMORRHOIDS A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
& Date is estimated.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:79.0 KG

PRE TO -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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:79.0 KG								
	DB	1 TO 112	112	112	R: RIGHT SIDED PNEUMONIA CAUSED BY STAPHYLOCOCCUS AUREUS S: 感染症および寄生虫症 P: ブドウ球菌性肺炎 L: Staphylococcus aureus pneumonia	E: 142 L: 31 Days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: STAPHYLOCOCCUS AUREUS A: NO REASONABLE POSSIBILITY
	BE	113 TO						

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:51.0 KG

PRE TO -1

DB 1 TO 112

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 30 mg QD								
[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:51.0 KG								
	BE	113 TO	13	125	R: ALLERGIC REACTION TO DAIRY S: 免疫系障害 P: 乳アレルギー L: Milk allergy	E: 128 L: 4 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening O: NEW FOOD ALLERGY A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:71.8 KG

PRE	TO -1
DB	1 TO 113
BE	114 TO 495

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 30 mg QD								
[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:71.8 KG								
	FU	496 TO	1	496	R: ECZEMA HERPETICUM ON SCALP S: 感染症および寄生虫症 P: ヘルペス性状湿疹 L: Eczema herpeticum	O: Yes	T: Grade 2 R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY E: No

Note: Treatment-emergent 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:75.9 KG

PRE TO -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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:75.9 KG								
	DB	1 TO 48	36	36	R: GASTRIC TUMOR (MALIGNANT) S: 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） P: 胃癌 L: Malignant neoplasm of stomach	O: Yes	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: Yes, Hospitalization or prolonged hospitalization O: REFLUX ESOPHAGITIS WITH MUCOSAL PROLIFERATION AND MUCOSAL HEMORRHAGES AND EROSIVE PANGASTRITIS WITH ULCEROUS GASTRIC ULCER ARE CRUCIAL F A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:75.9 KG

FU 49 TO

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:84.5 KG								
	PRE	TO -1						
	DB	1 TO 111						
	BE	112 TO	616	727	R: INTESTINAL PERFORATION S: 胃腸障害 P: 腸管穿孔 L: Intestinal perforation	E: 731 L: 5 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: SIGMOIDECTOMY	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: DIVERTICULITIS E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:MALE RACE:ASIAN WEIGHT:67.4 KG

PRE TO -1

DB 1 TO 112

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted] AGE:3[redacted] SEX:MALE RACE:ASIAN WEIGHT:67.4 KG								
	BE	113 TO	37	149	R: RETINAL DETACHMENT S: 眼障害 P: 網膜剥離 L: Retinal detachment	E: 169 L: 21 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: RETINAL DETACHMENT IS ONE OF THE OCULAR COMPLICATIONS OF AD. THE PATIENT HAS SEVERE AD, ESPECIALLY IN HIS FACE. HE OFTEN RUBS HIS EYES. SO HIS RETINAL DETACHMENT IS POSSIBLY DUE TO EYE RUBBING. A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:FEMALE RACE:MULTIPLE WEIGHT:57.0 KG

PRE TO -1

DB 1 TO 111

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:2[redacted] SEX:FEMALE RACE:MULTIPLE WEIGHT:57.0 KG								
	BE	112 TO	231	342	R: ACUTE DISTAL TIP FIBULAR FRACTURE, DISTAL TIBIAL FRACTURES S: 傷害、中毒および処置合併症 P: 腓骨骨折 L: Fibula fracture		T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: PATIENT WAS SKATEBOARDING AT 16:30 WHEN THE SKATEBOARD FLEW OUT FROM UNDER HER CAUSING HER TO LAND ON THE EDGE OF HER LEFT FOOT AND FALL ON TOP OF HER LEFT ANKLE. A: NO REASONABLE POSSIBILITY E: N

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:2[redacted] SEX:FEMALE RACE:MULTIPLE WEIGHT:57.0 KG								
	BE	112 TO	231	342	R: ACUTE DISTAL TIP FIBULAR FRACTURE, DISTAL TIBIAL FRACTURES S: 傷害、中毒および処置合併症 P: 脛骨骨折 L: Tibia fracture		T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: PATIENT WAS SKATEBOARDING AT 16:30 WHEN THE SKATEBOARD FLEW OUT FROM UNDER HER CAUSING HER TO LAND ON THE EDGE OF HER LEFT FOOT AND FALL ON TOP OF HER LEFT ANKLE. A: NO REASONABLE POSSIBILITY E: N

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:FEMALE RACE:MULTIPLE WEIGHT:54.3 KG

PRE	TO -1
DB	1 TO 112
BE	113 TO 135

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted] AGE:5[redacted] SEX:FEMALE RACE:MULTIPLE WEIGHT:54.3 KG								
	FU	136 TO	5	140	R: TOXIC EPIDERMAL NECROLYSIS S: 皮膚および皮下組織障害 P: 中毒性表皮壊死融解症 L: Toxic epidermal necrolysis	E: 149 L: 10 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: Yes, Hospitalization or prolonged hospitalization O: ANTIBIOTIC ALLERGY (CEFADROXIL) A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted]	AGE:2[redacted] SEX:MALE RACE:MULTIPLE WEIGHT:74.5 KG							
	PRE	TO -1						
	DB	1 TO 111	96	96	R: ACUTE APPENDICITIS S: 感染症および寄生虫症 P: 虫垂炎 L: Acute appendicitis	E: 100 L: 5 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: APPENDIX IMFLAMMATION A: NO REASONABLE POSSIBILITY E: No
	BE	112 TO						

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:151.0 KG

PRE TO -1

DB 1 TO 113

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:151.0 KG								
	BE	114 TO 371	257	370	R: COVID-19 INFECTION S: 感染症および寄生虫症 P: コロナウイルス感染 L: Coronavirus infection	E: 399 L: 30 Days	T: Grade 4 R: NO REASONABLE POSSIBILITY A: STUDY DRUG WAS INITIALLY STOPPED DUE TO COVID-19 INFECTION, BUT WAS DISCONTINUED DUE TO HEART ATTACK O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening O: COVID 19 VIRUS E: Yes

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:151.0 KG								
	FU	372 TO	13	384	R: RENAL FAILURE S: 腎および尿路障害 P: 腎不全 L: Renal failure	E: 399 L: 16 Days	T: Grade 4 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening O: SUSPECTED ITS A SECONDARY TO COVID RELATED A: NO REASONABLE POSSIBILITY E: Yes

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:151.0 KG								
	FU	372 TO	28	399	R: HEART ATTACK S: 心臓障害 P: 心筋梗塞 L: Heart attack	E: 399 L: 1 Day	T: Grade 5 R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: DISCONTINUED STUDY	S: Yes, Hospitalization or prolonged hospitalization, Life threatening, Death of subject O: PNEUMONIA DUE TO COVID-19 VIRUS A: NO REASONABLE POSSIBILITY E: Yes

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:151.0 KG								
	FU	372 TO	28	399	R: LEFT SIDED TENSION PNEUMOTHORAX S: 呼吸器、胸郭および縦隔障害 P: 気胸 L: Tension pneumothorax	E: 399 L: 1 Day	T: Grade 4 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: PULMONOLOGY PLACED LEFT-SIDED CHEST TUBE	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening O: RESPIRATORY FAILURE DUE TO COVID 19 A: NO REASONABLE POSSIBILITY E: Yes

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:110.0 KG

PRE TO -1

DB 1 TO 112

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:110.0 KG								
	BE	113 TO 199	86	198	R: MUSCULAR PAIN UPPER LEG LEFT - CAUSE UNKNOWN S: 筋骨格系および結合組織障害 P: 筋肉痛 L: Myalgia of lower extremities	E: 259 L: 62 Days	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, CURATIVE EURYTHMIE, RHYTMIC MASSAGE, PHYSICAL THERAPY)	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY
	FU	200 TO						

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch	---- Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted]	AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:51.0 KG							
	PRE	TO -1						
	DB	1 TO 111						
	BE	112 TO 183	72	183	R: COMMUNITY-ACQUIRED BILATERAL PNEUMONIA S: 感染症および寄生虫症 P: 肺炎 L: Community acquired pneumonia	O: Yes	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: Yes, Hospitalization or prolonged hospitalization A: REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:51.0 KG

FU 184 TO

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:MALE RACE:ASIAN WEIGHT:68.7 KG

PRE TO -1

DB 1 TO 109

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 30 mg QD								
[redacted] AGE:2[redacted] SEX:MALE RACE:ASIAN WEIGHT:68.7 KG								
	BE	110 TO	134	243	R: LEFT HERPETIC CONJUNCTIVITIS S: 感染症および寄生虫症 P: ヘルペス眼感染 L: Herpes ophthalmic	E: 254 L: 12 Days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, OPTHAMOLOGY REVIEW AND TREATMENT)	S: Yes, Important medical or surgical intervention O: HSV INFECTION ON A BACKGROUND OF KNOWN COLD SORES A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 30 mg QD								
[redacted] AGE:2[redacted] SEX:MALE RACE:ASIAN WEIGHT:68.7 KG								
	BE	110 TO	134	243	R: WORSENING OF ECZEMA HERPETICUM S: 感染症および寄生虫症 P: ヘルペス性状湿疹 L: Eczema herpeticum	E: 254 L: 12 Days	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, HOSPITILISATION)	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 30 mg QD								
[redacted] AGE:2[redacted] SEX:MALE RACE:ASIAN WEIGHT:68.7 KG								
	BE	110 TO	331	440	R: RIGHT HSV PERIORBITAL INFECTION S: 感染症および寄生虫症 P: 単純ヘルペス L: Herpes simplex	E: 448 L: 9 Days	T: Grade 3 R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Important medical or surgical intervention A: NO REASONABLE POSSIBILITY E: No
			341	450	R: PERIORBITAL (BILATERAL) FLARE OF HSV S: 感染症および寄生虫症 P: 単純ヘルペス L: Herpes simplex	E: 453 L: 4 Days	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Important medical or surgical intervention A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted]	AGE:3[redacted] SEX:MALE RACE:ASIAN WEIGHT:76.1 KG							
	PRE	TO -1						
	DB	1 TO 112	42	42	R: ALLERGIC REACTION TO PINE NUTS S: 免疫系障害 P: 食物アレルギー L: Allergy to nuts	E: 42 L: 1 Day	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Important medical or surgical intervention O: ALLERGIC REACTION TO PINE NUTS KNOWN MEDICAL HISTORY A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:MALE RACE:ASIAN WEIGHT:76.1 KG

BE 113 TO

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:72.0 KG								
	PRE	TO -1						
	DB	1 TO 111						
	BE	112 TO	10	121	R: PNEUMONIA S: 感染症および寄生虫症 P: 肺炎 L: Pneumonia	E: 138 L: 18 Days	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: LOWER RESPIRATORY TRACT INFECTION A: REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:81.3 KG

PRE TO -1

DB 1 TO 112

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 30 mg QD								
[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:81.3 KG								
	BE	113 TO	159	271	R: RIGHT COMMINUTED DISTAL RADIUS FRACTURE S: 傷害、中毒および処置合併症 P: 橈骨骨折 L: Radius fracture	E: 356 L: 86 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, SURGICAL REPAIR)	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: TRAUMA A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted]	AGE:3[redacted] SEX:MALE RACE:ASIAN WEIGHT:87.7 KG							
	PRE	TO -1						
	DB	1 TO 113	9	9	R: ALLERGIC REACTION TO ALLERGEN INJECTED BY FAMILY PHYSICIAN S: 免疫系障害 P: 過敏症 L: Allergic reaction	E: 9 L: 1 Day I: Yes	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Life threatening O: REACTION TO ALLERGEN GIVEN BY HIS ALLERGY SPECIALIST A: NO REASONABLE POSSIBILITY E: No
	BE	114 TO						

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted] AGE:1[redacted] SEX:MALE RACE:MULTIPLE WEIGHT:68.5 KG								
	PRE	TO -1						
	DB	1 TO 112						
	BE	113 TO	331	443	R: INCREASED LEVEL OF CREATINE KINASE S: 臨床検査 P: 血中クレアチンホスホキナーゼ増加 L: Creatine kinase increased	E: 456 L: 14 Days	T: Grade 4 R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY E: No

Note: Treatment-emergent 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 30 mg QD								
[redacted] AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:82.8 KG								
	PRE	TO -1						
	DB	1 TO 112						
	BE	113 TO 321	206	318	R: PYELONEPHRITIS LEFT S: 感染症および寄生虫症 P: 腎盂腎炎 L: Pyelonephritis	E: 329 L: 12 Days	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:82.8 KG

FU 322 TO

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:76.4 KG

PRE TO -1

DB 1 TO 111

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:76.4 KG								
	BE	112 TO	402	513	R: DISSEMINATED HERPES ZOSTER, CUTANEOUS S: 感染症および寄生虫症 P: 皮膚播種性帯状疱疹 L: Herpes zoster cutaneous disseminated	E: 534 L: 22 Days	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention A: REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:76.3 KG

PRE TO -1

DB 1 TO 112

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 30 mg QD								
[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:76.3 KG								
	BE	113 TO	362	474	R: MILD DIVERCUTILITIS S: 感染症および寄生虫症 P: 憩室炎 L: Diverticulitis	I: Yes	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: HISTORY OF ULCERATIVE COLITIS, THUS DIVERTICULITIS LIKELY TO BE RELATED TO ULCERATIVE COLITIS A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 30 mg QD								
[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:76.3 KG								
	BE	113 TO	362	474	R: MILD DIVERCUTILITIS S: 感染症および寄生虫症 P: 憩室炎 L: Diverticulitis	I: Yes	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: HISTORY OF ULCERATIVE COLITIS, THUS DIVERTICULITIS LIKELY TO BE RELATED TO ULCERATIVE COLITIS A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:56.0 KG

PRE TO -1

DB 1 TO 111

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo/UPA 30 mg QD								
[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:56.0 KG								
	BE	112 TO	351	462	R: FRACTURED FOREARM RIGHT S: 傷害、中毒および処置合併症 P: 前腕骨折 L: Forearm fracture	E: 505 L: 44 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, OPERATION: RESETTING OF BROKEN LIMB)	S: Yes, Hospitalization or prolonged hospitalization O: PATIENT SLIPPED AND FELL IN POOL AREA A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch	---- Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:74.0 KG								
	PRE	TO -1						
	DB	1 TO 113						
	BE	114 TO	216	329	R: RUPTURED ACHILLES TENDON S: 傷害、中毒および処置合併症 P: 腱断裂 L: Ruptured Achilles tendon	E: 356 L: 28 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: PLAYING FUSSBALL AKA SOCCER A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD								
[redacted]	AGE:1[redacted] SEX:FEMALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:76.2 KG							
	PRE	TO -1						
	DB	1 TO 112	82	82	R: WORSENING IMPETIGO AROUND LIPS S: 感染症および寄生虫症 P: 膿痂疹 L: Impetigo	E: 155 L: 74 Days	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY
	BE	113 TO 138						
	FU	139 TO						

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD								
[redacted] AGE:3[redacted] SEX:MALE RACE:ASIAN WEIGHT:76.0 KG								
	PRE	TO -1						
	DB	1 TO 114						
	BE	115 TO	43	157	R: PNEUMONIA S: 感染症および寄生虫症 P: 肺炎 L: Pneumonia		T: Grade 2 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: ASTHMA A: REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
被験者番号[redacted], [redacted]及び[redacted]は日本人であった。
相互参照：M16-045 試験 CSR W52 Table 14.3 2.25.1

表 2.7.4.7-39. 全試験期間中（投与 16 週時データカットオフまで）の重篤な有害事象の一覧表（Safety_DB_M 集団）：M16-047 試験

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:86.0 KG

PRE TO -1

DB 1 TO 109

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:86.0 KG								
	BE	110 TO	1	110	R: RENAL COLIC S: 腎および尿路障害 P: 腎仙痛 L: Renal colic	E: 113 L: 4 Days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, NOLOTIL 1 CP/8H ENANYUM 1CP/12 H OMEPRAZOL 20 MG 1 CP/24 H)	S: Yes, Hospitalization or prolonged hospitalization O: RENAL LITIASIS A: NO REASONABLE POSSIBILITY E: No

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:MALE RACE:ASIAN WEIGHT:77.0 KG

PRE TO -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 study drug and no more than 30 days after the last dose of study drug. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:2[redacted] SEX:MALE RACE:ASIAN WEIGHT:77.0 KG								
	DB	1 TO 105	43	43	R: RETINAL DETACHMENT OF LEFT EYE S: 眼障害 P: 網膜剥離 L: Retinal detachment	E: 47 L: 5 Days	T: Grade 3 R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, SURGERY)	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: PATIENT WOKE UP AND COULD NOT SEE CLEARLY, SIGHT WAS BLURRED A: NO REASONABLE POSSIBILITY
	BE	106 TO						

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:60.4 KG								
	PRE	TO -1						
	DB	1 TO 112	53	53	R: PANCYTOPENIA. S: 血液およびリンパ系障害 P: 汎血球減少症 L: Pancytopenia	E: 63 L: 11 Days I: Yes	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: INFECTION A: NO REASONABLE POSSIBILITY
	BE	113 TO						

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 30 mg QD + TCS								
[redacted]	AGE:2[redacted] SEX:MALE RACE:ASIAN WEIGHT:61.8 KG							
	PRE	TO -1						
	DB	1 TO 124	21	21	R: EZCEMA FLARE S: 皮膚および皮下組織障害 P: 湿疹 L: Eczema aggravated	E: 57 L: 37 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY E: No
	BE	125 TO						

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:60.5 KG

PRE TO -1

DB 1 TO 116

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:60.5 KG								
	BE	117 TO 215	25	141	R: STERNAL FRACTURE, VERTEBRAL FRACTURES S: 傷害、中毒および処置合併症 P: 脊椎骨折 L: Fracture of vertebra	E: 194 L: 54 Days	T: Grade 4 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening O: TRAMPOLINE INJURY A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:60.5 KG								
	BE	117 TO 215	25	141	R: STERNAL FRACTURE, VERTEBRAL FRACTURES S: 傷害、中毒および処置合併症 P: 胸骨骨折 L: Sternal fracture	E: 194 L: 54 Days	T: Grade 4 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening O: TRAMPOLINE INJURY A: NO REASONABLE POSSIBILITY
	FU	216 TO						

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:2[redacted] SEX:MALE RACE:ASIAN WEIGHT:64.0 KG								
	PRE	TO -1						
	DB	1 TO 119						
	BE	120 TO	5	124	R: RHEGMATOGENOUS RETINAL DETACHMENT OF THE RIGHT EYE S: 眼障害 P: 裂孔原性網膜剥離 L: Rhegmatogenous retinal detachment	E: 130 L: 7 Days	T: Grade 3 R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:2[redacted] SEX:MALE RACE:ASIAN WEIGHT:64.0 KG								
	BE	120 TO	82	201	R: RHEGMATOGENOUS RETINAL DETACHMENT OF LEFT EYE S: 眼障害 P: 裂孔原性網膜剥離 L: Rhegmatogenous retinal detachment	E: 208 L: 8 Days	T: Grade 3 R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:110.2 KG								
	PRE	TO -1						
	DB	1 TO 110						
	BE	111 TO 152						
	FU	153 TO	3	155	R: ACUTE BRONCHITIS DUE TO RHINOVIRUS S: 感染症および寄生虫症 P: 気管支炎 L: Acute bronchitis	O: Yes	T: Grade 4 R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:110.2 KG								
	FU	153 TO	3	155	R: ACUTE BRONCHITIS DUE TO RHINOVIRUS S: 感染症および寄生虫症 P: ライノウイルス感染 L: Rhinovirus infection	O: Yes	T: Grade 4 R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:91.2 KG								
	PRE	TO -1						
	DB	1 TO 66	7	7	R: COLON ADENOCARCINOMA S: 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） P: 結腸腺癌 L: Adenocarcinoma of colon	O: Yes	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Persistent or significant disability/incapacity, Important medical or surgical intervention A: NO REASONABLE POSSIBILITY
	FU	67 TO						

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch	---- Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:52.9 KG								
	PRE	TO -1						
	DB	1 TO 114						
	BE	115 TO	101	215	R: SUPERINFECTED ECZEMA OF THE HANDS S: 感染症および寄生虫症 P: 感染性湿疹 L: Infected eczema	E: 218 L: 4 Days	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY E: No

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 15 mg QD + TCS								
[redacted] AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:70.5 KG								
	PRE	TO -1						
	DB	1 TO 114	74	74	R: PERIANAL ABCESS S: 感染症および寄生虫症 P: 肛門膿瘍 L: Perianal abscess	E: 85 L: 12 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, SURGICAL OPERATION OF ANAL ABSCESS)	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: PREVIOUS OPERATION 1,5 YEARS AGO NOT SUCCESSFUL A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 15 mg QD + TCS								
[redacted] AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:70.5 KG								
	BE	115 TO	41	155	R: ANAL ABSCESS S: 感染症および寄生虫症 P: 肛門膿瘍 L: Anal abscess	E: 196 L: 42 Days I: Yes	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, OPERATION)	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: PREVIOUS OPERATION NOT SUCCESSFUL A: NO REASONABLE POSSIBILITY E: No

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted]	AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:67.5 KG							
	PRE	TO -1						
	DB	1 TO 114	12	12	R: ANAPHYLACTIC ALLERGY DUE TO EATING PEANUTS S: 免疫系障害 P: アナフィラキシー反応 L: Anaphylactic reaction to food	E: 13 L: 2 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: EATING PEANUTS A: NO REASONABLE POSSIBILITY
	BE	115 TO						

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:77.3 KG								
	PRE	TO -1						
	DB	1 TO 115	93	93	R: RENAL CALCULI W/ HYDRONEPHROSIS S: 腎および尿路障害 P: 水腎症 L: Hydronephrosis	E: 98 L: 6 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: UNKNOWN - PER SUB-I, EVENT COULD POSSIBLY HAVE BEEN CAUSED BY DEHYDRATION A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:77.3 KG								
	DB	1 TO 115	93	93	R: RENAL CALCULI W/ HYDRONEPHROSIS S: 腎および尿路障害 P: 腎結石症 L: Renal calculi	E: 98 L: 6 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: UNKNOWN - PER SUB-I, EVENT COULD POSSIBLY HAVE BEEN CAUSED BY DEHYDRATION A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:77.3 KG								
	BE	116 TO	107	222	R: CORNEAL ULCER - LEFT S: 眼障害 P: 潰瘍性角膜炎 L: Corneal ulcer		T: Grade 4 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, INPATIENT ADMISSION)	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY E: No

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:77.3 KG								
	BE	116 TO	247	362	R: RESPIRATORY, THORACIC, AND MEDIASTINAL DISORDERS, OTHER, PNEUMONIA S: 感染症および寄生虫症 P: 肺炎 L: Pneumonia	E: 383 L: 22 Days	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: NONE	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention A: REASONABLE POSSIBILITY E: No

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS								
[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:89.4 KG								
	PRE	TO -1						
	DB	1 TO 71	69	69	R: PNEUMONIA S: 感染症および寄生虫症 P: 肺炎 L: Pneumonia	O: Yes	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: COPD AND CIGARETTE USE A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS								
[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:89.4 KG								
	FU	72 TO	10	81	R: ACUTE RESPIRATORY FAILURE S: 呼吸器、胸郭および縦隔障害 P: 急性呼吸不全 L: Acute respiratory failure	E: 89 L: 9 Days	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: SECONDARY TO PNEUMONIA A: NO REASONABLE POSSIBILITY
			13	84	R: SEPSIS WITH MRSA S: 感染症および寄生虫症 P: ブドウ球菌性敗血症 L: Sepsis MRSA	O: Yes	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS								
[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:62.0 KG								
	PRE	TO -1						
	DB	1 TO 92	83	83	R: URINARY INFECTION S: 感染症および寄生虫症 P: 尿路感染 L: Urinary infection	E: 85 L: 3 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY
	FU	93 TO						

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:52.0 KG								
	PRE	TO -1						
	DB	1 TO 79	13	13	R: TONSILLAR PHLEGMON INFECTION, THROAT PAIN SINCE ONE DAY S: 感染症および寄生虫症 P: 扁桃周囲膿瘍 L: Peritonsillar abscess	E: 16 L: 4 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: THE CAUSE OF EVENT IS STILL UNKNOWN A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:52.0 KG								
	DB	1 TO 79	13	13	R: TONSILLAR PHLEGMON INFECTION, THROAT PAIN SINCE ONE DAY S: 呼吸器、胸郭および縦隔障害 P: 口腔咽頭痛 L: Throat pain	E: 16 L: 4 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: THE CAUSE OF EVENT IS STILL UNKNOWN A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:52.0 KG								
	DB	1 TO 79	79	79	R: OVERDOSE BY DRUGS (PARACETAMOL, IBUPROFENE, TRAMADOL) S: 傷害、中毒および処置合併症 P: 過量投与 L: Drug overdose	E: 81 L: 3 Days	T: Grade 4 R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening A: NO REASONABLE POSSIBILITY
	FU	80 TO						

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:65.0 KG								
	PRE	TO -1						
	DB	1 TO 114						
	BE	115 TO 253						
	FU	254 TO	6	259	R: ELECTIVE ABORTION S: 外科および内科処置 P: 人工流産 L: Elective abortion	E: 259 L: 1 Day	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: DISCONTINUED STUDY	S: Yes, Important medical or surgical intervention O: PATIENT DECISION A: NO REASONABLE POSSIBILITY E: No

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 30 mg QD + TCS								
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:63.6 KG							
	PRE	TO -1						
	DB	1 TO 112	22	22	R: FLARE ATOPICAL DERMATITIS WITH ERYTHRODERMA S: 皮膚および皮下組織障害 P: 紅皮症型アトピー性皮膚炎 L: Erythrodermic atopic dermatitis	E: 38 L: 17 Days	T: Grade 4 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: FLARE ATOPICAL DERMATITIS A: NO REASONABLE POSSIBILITY
	BE	113 TO						

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 15 mg QD + TCS								
[redacted] AGE:6[redacted] SEX:FEMALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:64.0 KG								
	PRE	TO -1						
	DB	1 TO 110	24	24	R: ATERIAL THROMBOSIS IN A STENT S: 一般・全身障害および投与部位の状態 P: 血管ステント血栓症 L: Vascular stent thrombosis	E: 65 L: 42 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: MEDICAL HISTORY OF PERIPHERAL ARTERY DISEASE A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 15 mg QD + TCS								
[redacted] AGE:6[redacted] SEX:FEMALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:64.0 KG								
	DB	1 TO 110	58	58	R: RIGHT GROIN HEMATOMA S: 血管障害 P: 血腫 L: Groin hematoma	E: 65 L: 8 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: REPAIR ANTERIOR/SUPERIOR FEMORAL ARTERY	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening O: ANTERIOR/SUPERIOR FEMORAL ARTERY INJURY AFTER ANGIOGRAM. A: NO REASONABLE POSSIBILITY
	BE	111 TO 167						
	FU	168 TO						

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch	---- Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:64.5 KG								
	PRE	TO -1						
	DB	1 TO 117	48	48	R: ACUTE APPENDICITIS S: 感染症および寄生虫症 P: 虫垂炎 L: Acute appendicitis	E: 49 L: 2 Days	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: LAPAROSCOPIC APPENDECTOMY	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention A: NO REASONABLE POSSIBILITY
	BE	118 TO 194						
	FU	195 TO						

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 30 mg QD + TCS								
[redacted]	AGE:2[redacted] SEX:MALE RACE:ASIAN WEIGHT:76.0 KG							
	PRE	TO -1						
	DB	1 TO 112	18	18	R: ANAPHYLACTIC REACTION TO PEANUTS S: 免疫系障害 P: アナフィラキシー反応 L: Anaphylactic reaction to food	E: 18 L: 1 Day	T: Grade 4 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Life threatening O: PEANUT ALLERGY A: NO REASONABLE POSSIBILITY E: No
	BE	113 TO						

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:100.2 KG								
	PRE	TO -1						
	DB	1 TO 110						
	BE	111 TO 328	218	328	R: STROKE S: 神経系障害 P: 脳血管発作 L: Stroke	O: Yes	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: NONE	S: Yes, Hospitalization or prolonged hospitalization, Life threatening O: CARDIAC HISTORY INDICATES IT WAS CARDIAC RELATED A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:100.2 KG

FU 329 TO

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: Placebo + TCS/UPA 30 mg QD + TCS

[redacted] AGE:4[redacted] SEX:MALE RACE:ASIAN WEIGHT:64.1 KG

PRE TO -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 study drug and no more than 30 days after the last dose of study drug. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 30 mg QD + TCS								
[redacted] AGE:4[redacted] SEX:MALE RACE:ASIAN WEIGHT:64.1 KG								
	DB	1 TO 109	62	62	R: RIGHT RHEGMATOGENOUS RETINAL DETACHMENT S: 眼障害 P: 裂孔原性網膜剥離 L: Rhegmatogenous retinal detachment		T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, RIGHT VITREOUS SURGERY)	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: WE CONSIDER RETINAL DETACHMENT IS DUE TO SCRATCHING. THERE IS NO REASONABLE RELATION BETWEEN RETINAL DETACHMENT AND STUDY DRUG. A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: Placebo + TCS/UPA 30 mg QD + TCS

[redacted] AGE:4[redacted] SEX:MALE RACE:ASIAN WEIGHT:64.1 KG

BE 110 TO

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted]	AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:72.8 KG							
	PRE	TO -1						
	DB	1 TO 115	37	37	R: STREPTOCOCCUS PHARYNGITIS S: 感染症および寄生虫症 P: レンサ球菌性咽頭炎 L: Streptococcal pharyngitis	E: 45 L: 9 Days	T: Grade 4 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: EXPOSURE TO BACTERIA A: NO REASONABLE POSSIBILITY
	BE	116 TO						

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:87.0 KG								
	PRE	TO -1						
	DB	1 TO 104	100	100	R: PLEURAL EFFUSION S: 呼吸器、胸郭および縦隔障害 P: 胸水 L: Pleural effusion	E: 102 L: 3 Days	T: Grade 3 R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY
	FU	105 TO						

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch	---- Interval	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:84.0 KG								
	PRE	TO -1						
	DB	1 TO 113						
	BE	114 TO 204	78	191	R: WORSENING OF ATOPIC DERMATITIS S: 皮膚および皮下組織障害 P: アトピー性皮膚炎 L: Dermatitis atopic aggravated	O: Yes	T: Grade 4 R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: Yes, Hospitalization or prolonged hospitalization O: ATOPIC DERMATITIS A: NO REASONABLE POSSIBILITY
	FU	205 TO						

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:67.8 KG								
	PRE	TO -1						
	DB	1 TO 113						
	BE	114 TO 208	79	192	R: EXACERBATION ECZEMA S: 皮膚および皮下組織障害 P: 湿疹 L: Eczema exacerbated	E: 241 L: 50 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: STUDY MEDICATION WAS ALREADY WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, HOSPITALIZATION)	S: Yes, Hospitalization or prolonged hospitalization O: WITHDRAWN OF STUDY MEDICATION A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:67.8 KG

FU 209 TO

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:91.6 KG

PRE TO -1

DB 1 TO 113

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:91.6 KG								
	BE	114 TO	290	403	R: LEFT DISTAL FEMUR FRACTURE S: 傷害、中毒および処置合併症 P: 大腿骨骨折 L: Femur fracture	E: 414 L: 12 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: NONE	S: Yes, Hospitalization or prolonged hospitalization, Persistent or significant disability/incapacity, Important medical or surgical intervention O: [redacted]: PT FELL AT HOME AND WAS HOSPITALIZED UNTIL [redacted] & THEN TX TO REHAB [redacted]. ADMITTED BACK TO HOSP ON [redacted] FOR SCHEDULED SURGERY AND D/C

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS								
[redacted]	AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:91.3 KG							
	PRE	TO -1						
	DB	1 TO 83	82	82	R: ERYTHRODERMA S: 皮膚および皮下組織障害 P: 全身性剥脱性皮膚炎 L: Erythroderma	O: Yes I: Yes	T: Grade 4 R: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: Yes, Hospitalization or prolonged hospitalization O: INADEQUATE TREATMENT FOR ATOPIC DERMATITIS A: NO REASONABLE POSSIBILITY
	FU	84 TO						

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:57.5 KG								
	PRE	TO -1						
	DB	1 TO 110						
	BE	111 TO 126	16	126	R: FURTHER DECREASE OF HAEMOGLOBIN LEVEL S: 臨床検査 P: ヘモグロビン減少 L: Haemoglobin decreased	O: Yes	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: DISCONTINUED STUDY	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY
	FU	127 TO						

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:2[redacted] SEX:MALE RACE:ASIAN WEIGHT:48.5 KG								
	PRE	TO -1						
	DB	1 TO 112						
	BE	113 TO	122	234	R: CUTANEOUS GENERALIZED HERPES ZOSTER S: 感染症および寄生虫症 P: 皮膚播種性帯状疱疹 L: Herpes zoster cutaneous disseminated	E: 251 L: 18 Days	T: Grade 3 R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization A: REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: Placebo + TCS/UPA 30 mg QD + TCS

[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:71.8 KG

PRE TO -1

DB 1 TO 108

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 30 mg QD + TCS								
[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:71.8 KG								
	BE	109 TO	187	295	R: PALPITATIONS S: 心臓障害 P: 動悸 L: Palpitations	I: Yes	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, CONCOMITANT MEDICATION OR THERAPY DISCONTINUED)	S: Yes, Hospitalization or prolonged hospitalization O: THERE IS NPO OTHER CAUSE OF EVENT, NO OTHER RISK FACTORS A: NO REASONABLE POSSIBILITY E: No

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 30 mg QD + TCS								
[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:71.8 KG								
	BE	109 TO	298	406	R: PALPITATIONS S: 心臓障害 P: 動悸 L: Palpitations	E: 407 L: 2 Days I: Yes	T: Grade 2 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: PALPITATIONS A: NO REASONABLE POSSIBILITY E: No

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:113.0 KG								
	PRE	TO -1						
	DB	1 TO 112						
	BE	113 TO	275	387	R: MIGRENE S: 神経系障害 P: 片頭痛 L: Migraine	E: 388 L: 2 Days	T: Grade 1 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: STRESS AT WORK A: NO REASONABLE POSSIBILITY E: No

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch	---- Interval	RX Day of Day	Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS									
[redacted] AGE:2[redacted] SEX:MALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:71.5 KG									
	PRE	TO -1							
	DB	1 TO	93	93		R: ASTHMA ATTACK S: 呼吸器、胸郭および縦隔障害 P: 喘息 L: Asthmatic attack	E: 95 L: 3 Days	T: Grade 4 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: ASTHMA ATTACK A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:2[redacted] SEX:MALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:71.5 KG								
	DB	1 TO	102	102	R: STATUS ASTHMATICUS S: 呼吸器、胸郭および縦隔障害 P: 喘息発作重積 L: Status asthmaticus	E: 107 L: 6 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: STUDY TREATMENT ALREADY ON HOLD O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: EXPOSURE TO ALLERGEN A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 30 mg QD + TCS								
[redacted]	AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:120.0 KG							
	PRE	TO -1						
	DB	1 TO 112						
	BE	113 TO	256	368	R: BACTERIAL BURSITIS WITH ABSCESS OLECRANON RIGHT ELBOW S: 感染症および寄生虫症 P: 感染性滑液包炎 L: Bursitis infective	E: 371 L: 4 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: TRAUMA A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 30 mg QD + TCS								
[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:120.0 KG								
	BE	113 TO	256	368	R: BACTERIAL BURSITIS WITH ABSCESS OLECRANON RIGHT ELBOW S: 感染症および寄生虫症 P: 関節膿瘍 L: Joint abscess	E: 371 L: 4 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: TRAUMA A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch	---- Interval	RX Day of Onset Day	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:69.0 KG								
	PRE	TO -1						
	DB	1 TO 117						
	BE	118 TO	89	206	R: FRACTURED LEFT CLAVICLE S: 傷害、中毒および処置合併症 P: 鎖骨骨折 L: Clavicle fracture	E: 223 L: 18 Days	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, SURGERY)	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: FELL OFF MOUNTAIN BIKE A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:6[redacted] SEX:MALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:110.9 KG								
	PRE	TO -1						
	DB	1 TO 89	77	77	R: WORSENING OF CONGESTIVE HEART FAILURE S: 心臓障害 P: うっ血性心不全 L: Congestive cardiac failure aggravated	O: Yes	T: Grade 3 R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: ICD PLACEMENT	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: PROGRESSION OF DISEASE A: NO REASONABLE POSSIBILITY
	FU	90 TO						

Note: Treatment-emergent adverse events are defined as any adverse events 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.
被験者番号[redacted]及び[redacted]は日本人であった。
相互参照：M16-047 試験 CSR W16 Table 14.3　2.24.1

表 2.7.4.7-40. 全試験期間中（投与 52 週時データカットオフまで）の重篤な有害事象の一覧表（ALL UPA_M 集団）：M16-047 試験

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:58.1 KG

PRE	TO -1
DB	1 TO 119
BE	120 TO 252

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:58.1 KG								
	FU	253 TO	1	253	R: WORSENED ATOPIC DERMATITIS S: 皮膚および皮下組織障害 P: アトピー性皮膚炎 L: Dermatitis atopic aggravated	O: Yes	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: NONE	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:86.0 KG

PRE TO -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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:86.0 KG								
	DB	1 TO 109	105	105	R: RENAL LITIASIS S: 腎および尿路障害 P: 腎結石症 L: Kidney stone	E: 116 L: 12 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, METILPREDNISOLONA|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, NOLOTIL 1 CP/8H ENANYUM 1CP/12 H OMEPRAZOL 20 MG 1 CP/24 H TAMSULOSINA 0.4MG/24H)	S: Yes, Hospitalization or prolonged hospitalization O: RENAL LITIASIS A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:86.0 KG

BE 110 TO

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:MALE RACE:ASIAN WEIGHT:77.0 KG

PRE TO -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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:2[redacted] SEX:MALE RACE:ASIAN WEIGHT:77.0 KG								
	DB	1 TO 105	43	43	R: RETINAL DETACHMENT OF LEFT EYE S: 眼障害 P: 網膜剥離 L: Retinal detachment	E: 47 L: 5 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|REASONABLE POSSIBILITY, Hydrocortisone acetate|REASONABLE POSSIBILITY, Mometasone furoate|REASONABLE POSSIBILITY, Pimecrolimus|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, SURGERY)	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: PATIENT WOKE UP AND COULD NOT SEE CLEARLY, SIGHT WAS BLURRED A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:MALE RACE:ASIAN WEIGHT:77.0 KG

BE 106 TO

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:60.4 KG

PRE TO -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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:60.4 KG								
	DB	1 TO 112	53	53	R: PANCYTOPENIA. S: 血液およびリンパ系障害 P: 汎血球減少症 L: Pancytopenia	E: 63 L: 11 Days I: Yes	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Betamethasone valerate|NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: INFECTION A: NO REASONABLE POSSIBILITY
	BE	113 TO						

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:4[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:67.1 KG

PRE TO -1

DB 1 TO 112

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:4[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:67.1 KG								
	BE	113 TO 408	296	408	R: HERPES ZOSTER S: 感染症および寄生虫症 P: 帯状疱疹 L: Herpes zoster	E: 431 L: 24 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Tacrolimus|NO REASONABLE POSSIBILITY, METHYLPREDNISOLONE|NO REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, CONCOMITANT MEDICATION OR THERAPY DI	S: Yes, Hospitalization or prolonged hospitalization O: IMMUNOSUPPRESSANT A: REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:4[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:67.1 KG

FU 409 TO

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: Placebo + TCS/UPA 15 mg QD + TCS

[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:90.0 KG

PRE TO -1

DB 1 TO 100

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 15 mg QD + TCS								
[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:90.0 KG								
	BE	101 TO	227	327	R: LATE PERIPROTHETIC INFECTION OF UPPER ANKLE JOINT PROSTHESIS LEFT S: 感染症および寄生虫症 P: 医療機器関連感染 L: Prosthesis related infection	E: 338 L: 12 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|REASONABLE POSSIBILITY, Prednicarbate|NO REASONABLE POSSIBILITY, Mometasone furoate|NO REASONABLE POSSIBILITY, BETAMETHASOME DIPROIONATE|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, PATIENT WAS HOSPITALIZE	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention A: REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 15 mg QD + TCS								
[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:90.0 KG								
	BE	101 TO	349	449	R: LATE PERIPROTHETIC INFECTION S: 感染症および寄生虫症 P: 医療機器関連感染 L: Prosthesis related infection	E: 455 L: 7 Days	T: Grade 2 R: UPADACITINIB/PLACEBO|REASONABLE POSSIBILITY, Prednicarbate|NO REASONABLE POSSIBILITY, Mometasone furoate|NO REASONABLE POSSIBILITY, Betamethasone valerate|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention A: REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:MALE RACE:ASIAN WEIGHT:64.2 KG

PRE TO -1

DB 1 TO 113

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:2[redacted] SEX:MALE RACE:ASIAN WEIGHT:64.2 KG								
	BE	114 TO	211	324	R: DUODENAL ULCER WITH BLEEDING S: 胃腸障害 P: 出血性十二指腸潰瘍 L: Duodenal ulcer bleeding	E: 390 L: 67 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|REASONABLE POSSIBILITY, Mometasone furoate|NO REASONABLE POSSIBILITY, Tacrolimus|NO REASONABLE POSSIBILITY, Desonide|NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY E: No

Note: Treatment-emergent 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: Placebo + TCS/UPA 30 mg QD + TCS

[redacted] AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:84.4 KG

PRE TO -1

DB 1 TO 113

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 30 mg QD + TCS [redacted] AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:84.4 KG								
	BE	114 TO	272	385	R: SPINAL STENOSIS S: 筋骨格系および結合組織障害 P: 脊柱管狭窄症 L: Spinal column stenosis	E: 411 L: 27 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, SURGERY [redacted]/20[redacted], HOSPITALIZED [redacted]/20[redacted] - [redacted]/20[redacted])	S: Yes, Hospitalization or prolonged hospitalization O: OSTEOARTHRITIS A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 30 mg QD + TCS [redacted] AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:84.4 KG								
	BE	114 TO	272	385	R: UNSTABLE SPONDYLOLISTHESIS S: 筋骨格系および結合組織障害 P: 脊椎すべり症 L: Spondylolisthesis	E: 411 L: 27 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, SURGERY [redacted]/20[redacted], HOSPITALIZATION [redacted]/20[redacted] - [redacted]/20[redacted])	S: Yes, Hospitalization or prolonged hospitalization O: OSTEOARTHRITIS E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:60.5 KG

PRE TO -1

DB 1 TO 116

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:60.5 KG								
	BE	117 TO 215	25	141	R: STERNAL FRACTURE, VERTEBRAL FRACTURES S: 傷害、中毒および処置合併症 P: 脊椎骨折 L: Fracture of vertebra	E: 194 L: 54 Days	T: Grade 4 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY, EUMOVATE|NO REASONABLE POSSIBILITY, NO OTHER TOPICAL STEROID IN USE|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening O: TRAMPOLINE INJURY A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:60.5 KG								
	BE	117 TO 215	25	141	R: STERNAL FRACTURE, VERTEBRAL FRACTURES S: 傷害、中毒および処置合併症 P: 胸骨骨折 L: Sternal fracture	E: 194 L: 54 Days	T: Grade 4 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY, EUMOVATE|NO REASONABLE POSSIBILITY, NO OTHER TOPICAL STEROID IN USE|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening O: TRAMPOLINE INJURY A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:60.5 KG

FU 216 TO

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:MALE RACE:ASIAN WEIGHT:64.0 KG

PRE TO -1

DB 1 TO 119

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:2[redacted] SEX:MALE RACE:ASIAN WEIGHT:64.0 KG								
	BE	120 TO	5	124	R: RHEGMATOGENOUS RETINAL DETACHMENT OF THE RIGHT EYE S: 眼障害 P: 裂孔原性網膜剥離 L: Rhegmatogenous retinal detachment	E: 130 L: 7 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|REASONABLE POSSIBILITY, Mometasone furoate|NO REASONABLE POSSIBILITY, Desonide|NO REASONABLE POSSIBILITY, Tacrolimus|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:2[redacted] SEX:MALE RACE:ASIAN WEIGHT:64.0 KG								
	BE	120 TO	82	201	R: RHEGMATOGENOUS RETINAL DETACHMENT OF LEFT EYE S: 眼障害 P: 裂孔原性網膜剥離 L: Rhegmatogenous retinal detachment	E: 208 L: 8 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|REASONABLE POSSIBILITY, Desonide|NO REASONABLE POSSIBILITY, Mometasone furoate|NO REASONABLE POSSIBILITY, Tacrolimus|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY E: No

Note: Treatment-emergent 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:110.2 KG

PRE	TO -1
DB	1 TO 110
BE	111 TO 152

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:110.2 KG								
	FU	153 TO	3	155	R: ACUTE BRONCHITIS DUE TO RHINOVIRUS S: 感染症および寄生虫症 P: 気管支炎 L: Acute bronchitis	O: Yes	T: Grade 4 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:110.2 KG								
	FU	153 TO	3	155	R: ACUTE BRONCHITIS DUE TO RHINOVIRUS S: 感染症および寄生虫症 P: ライノウイルス感染 L: Rhinovirus infection	O: Yes	T: Grade 4 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:91.2 KG								
	PRE	TO -1						
	DB	1 TO 66	7	7	R: COLON ADENOCARCINOMA S: 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） P: 結腸腺癌 L: Adenocarcinoma of colon	O: Yes	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Persistent or significant disability/incapacity, Important medical or surgical intervention A: NO REASONABLE POSSIBILITY
	FU	67 TO						

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:52.9 KG

PRE TO -1

DB 1 TO 114

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:WHITE WEIGHT:52.9 KG								
	BE	115 TO	101	215	R: SUPERINFECTED ECZEMA OF THE HANDS S: 感染症および寄生虫症 P: 感染性湿疹 L: Infected eczema	E: 218 L: 4 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|REASONABLE POSSIBILITY, Triamcinolone acetonide|REASONABLE POSSIBILITY, Hydrocortisone acetate|REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY E: No

Note: Treatment-emergent 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: Placebo + TCS/UPA 30 mg QD + TCS

[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:120.0 KG

PRE TO -1

DB 1 TO 112

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 30 mg QD + TCS [redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:120.0 KG								
	BE	113 TO	256	368	R: BACTERIAL BURSITIS WITH ABSCESS OLECRANON RIGHT ELBOW S: 感染症および寄生虫症 P: 感染性滑液包炎 L: Bursitis infective	E: 371 L: 4 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, NO REASONABLE POSSIBILITY|NO REASONABLE POSSIBILITY, NO REASONABLE POSSIBILITY|NO REASONABLE POSSIBILITY, NO REASONABLE POSSIBILITY|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: TRAUMA A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 30 mg QD + TCS [redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:120.0 KG								
	BE	113 TO	256	368	R: BACTERIAL BURSITIS WITH ABSCESS OLECRANON RIGHT ELBOW S: 感染症および寄生虫症 P: 関節膿瘍 L: Joint abscess	E: 371 L: 4 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, NO REASONABLE POSSIBILITY|NO REASONABLE POSSIBILITY, NO REASONABLE POSSIBILITY|NO REASONABLE POSSIBILITY, NO REASONABLE POSSIBILITY|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: TRAUMA A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 30 mg QD + TCS [redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:120.0 KG								
	BE	113 TO	361	473	R: CAUDA EQUINA SYNDROME S: 神経系障害 P: 馬尾症候群 L: Cauda equina syndrome	E: 479 L: 7 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Mometasone furoate|NO REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY, CLOBETASOL|NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, SURGERY)	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: PATIENT WORKS WITH CAR PARTS AND CAR TIRES, POSSIBLE CAUSE OF EVENT WAS WHILE LIFTING HEAVY PARTS A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 30 mg QD + TCS								
[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:120.0 KG								
	BE	113 TO	382	494	R: HERPES SIMPLEX INFECTION, FACE/UNDER LEFT EYE S: 感染症および寄生虫症 P: 単純ヘルペス L: Herpes simplex	I: Yes	T: Grade 3 R: UPADACITINIB/PLACEBO|REASONABLE POSSIBILITY, Mometasone furoate|NO REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY, CLOBETASOL PROPIONATE|NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY E: No

Note: Treatment-emergent 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: Placebo + TCS/UPA 15 mg QD + TCS

[redacted] AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:70.5 KG

PRE TO -1

DB 1 TO 114

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 15 mg QD + TCS [redacted] AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:70.5 KG								
	BE	115 TO	41	155	R: ANAL ABSCESS S: 感染症および寄生虫症 P: 肛門膿瘍 L: Anal abscess	E: 196 L: 42 Days I: Yes	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Mometasone furoate|NO REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, OPERATION)	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: PREVIOUS OPERATION NOT SUCCESSFUL A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:67.5 KG

PRE TO -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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:67.5 KG								
	DB	1 TO 114	12	12	R: ANAPHYLACTIC ALLERGY DUE TO EATING PEANUTS S: 免疫系障害 P: アナフィラキシー反応 L: Anaphylactic reaction to food	E: 13 L: 2 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Mometasone furoate|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: EATING PEANUTS A: NO REASONABLE POSSIBILITY
	BE	115 TO						

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:77.3 KG

PRE TO -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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:77.3 KG								
	DB	1 TO 115	93	93	R: RENAL CALCULI W/ HYDRONEPHROSIS S: 腎および尿路障害 P: 水腎症 L: Hydronephrosis	E: 98 L: 6 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: UNKNOWN - PER SUB-I, EVENT COULD POSSIBLY HAVE BEEN CAUSED BY DEHYDRATION A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:77.3 KG								
	DB	1 TO 115	93	93	R: RENAL CALCULI W/ HYDRONEPHROSIS S: 腎および尿路障害 P: 腎結石症 L: Renal calculi	E: 98 L: 6 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: UNKNOWN - PER SUB-I, EVENT COULD POSSIBLY HAVE BEEN CAUSED BY DEHYDRATION A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:77.3 KG								
	BE	116 TO	107	222	R: CORNEAL ULCER - LEFT S: 眼障害 P: 潰瘍性角膜炎 L: Corneal ulcer		T: Grade 4 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY, BETAMETHASONE DIPROPIONATE|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, INPATIENT ADMISSION)	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:77.3 KG								
	BE	116 TO	247	362	R: RESPIRATORY, THORACIC, AND MEDIASTINAL DISORDERS, OTHER, PNEUMONIA S: 感染症および寄生虫症 P: 肺炎 L: Pneumonia	E: 383 L: 22 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY, BETAMETHASONE DIPROPIONATE|NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: NONE	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention A: REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: Placebo + TCS/UPA 15 mg QD + TCS

[redacted] AGE:3[redacted] SEX:MALE RACE:ASIAN WEIGHT:48.6 KG

PRE TO -1

DB 1 TO 113

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 15 mg QD + TCS								
[redacted] AGE:3[redacted] SEX:MALE RACE:ASIAN WEIGHT:48.6 KG								
	BE	114 TO	336	449	R: TARSAL TUNNEL SYNDROME(RIGHT) S: 神経系障害 P: 足根管症候群 L: Tarsal tunnel syndrome	E: 681 L: 233 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Fluocinolone acetonide|NO REASONABLE POSSIBILITY, Dexamethasone|NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: THERE IS NO UNDERLYING DISEASE. IT IS POSSIBLE THAT THE LIFESTYLE OR WORK OF A CAREGIVER HAS CAUSED PROBLEMS. A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 15 mg QD + TCS								
[redacted] AGE:3[redacted] SEX:MALE RACE:ASIAN WEIGHT:48.6 KG								
	BE	114 TO	509	622	R: OLD LIGAMENT INJURY(RIGHT FOOT) S: 傷害、中毒および処置合併症 P: 靭帯損傷 L: Ligament injury	E: 681 L: 60 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Fluocinolone acetonide|NO REASONABLE POSSIBILITY, Dexamethasone|NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: NONE	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: THERE IS NO UNDERLYING DISEASE. IT IS POSSIBLE THAT THE LIFESTYLE OR WORK OF A CAREGIVER HAS CAUSED PROBLEMS. A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 15 mg QD + TCS								
[redacted] AGE:3[redacted] SEX:MALE RACE:ASIAN WEIGHT:48.6 KG								
	BE	114 TO	509	622	R: RIGHT PERONEAL NERVE PARESIS S: 神経系障害 P: 末梢神経不全麻痺 L: Peripheral nerve paresis	E: 681 L: 60 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Fluocinolone acetonide|NO REASONABLE POSSIBILITY, Dexamethasone|NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: NONE	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: THERE IS NO UNDERLYING DISEASE. IT IS POSSIBLE THAT THE LIFESTYLE OR WORK OF A CAREGIVER HAS CAUSED PROBLEMS. A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:66.0 KG

PRE TO -1

DB 1 TO 117

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:66.0 KG								
	BE	118 TO	402	519	R: WORSENING OF ATOPIC DERMATITIS, IMPETIGO, ACUT BACTERIAL INFECTION S: 感染症および寄生虫症 P: 細菌感染 L: Bacterial infection	E: 523 L: 5 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Hydrocortisone butyrate|NO REASONABLE POSSIBILITY, Mometasone furoate|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:66.0 KG								
	BE	118 TO	402	519	R: WORSENING OF ATOPIC DERMATITIS, IMPETIGO, ACUT BACTERIAL INFECTION S: 感染症および寄生虫症 P: 膿痂疹 L: Impetigo	E: 523 L: 5 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Hydrocortisone butyrate|NO REASONABLE POSSIBILITY, Mometasone furoate|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:1[redacted] SEX:MALE RACE:WHITE WEIGHT:66.0 KG								
	BE	118 TO	402	519	R: WORSENING OF ATOPIC DERMATITIS, IMPETIGO, ACUT BACTERIAL INFECTION S: 皮膚および皮下組織障害 P: アトピー性皮膚炎 L: Dermatitis atopic aggravated	E: 523 L: 5 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Hydrocortisone butyrate|NO REASONABLE POSSIBILITY, Mometasone furoate|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: NO REASONABLE POSSIBILITY A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: Placebo + TCS/UPA 30 mg QD + TCS

[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:83.3 KG

PRE TO -1

DB 1 TO 112

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 30 mg QD + TCS								
[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:83.3 KG								
	BE	113 TO	286	398	R: ACUTE RESPIRATORY DISTRESS SYNDROME S: 呼吸器、胸郭および縦隔障害 P: 急性呼吸窮迫症候群 L: Acute respiratory distress syndrome	E: 411 L: 14 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Important medical or surgical intervention O: COVID 19 VIRUS A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 30 mg QD + TCS [redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:83.3 KG								
	BE	113 TO	286	398	R: WORSENING COVID-19 INFECTION S: 感染症および寄生虫症 P: コロナウイルス感染 L: Coronavirus infection	E: 412 L: 15 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: COVID 19 VIRUS E: Yes

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 30 mg QD + TCS								
[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:83.3 KG								
	BE	113 TO	286	398	R: WORSENING PNEUMONIA S: 感染症および寄生虫症 P: 肺炎 L: Pneumonia aggravated	E: 412 L: 15 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: COVID 19 VIRUS A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 30 mg QD + TCS [redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:83.3 KG								
	BE	113 TO	296	408	R: NON-SUSTAINED VENTRICULAR TACHYCARDIA S: 心臓障害 P: 心室性頻脈 L: Non-sustained ventricular tachycardia	E: 408 L: 1 Day	T: Grade 2 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Important medical or surgical intervention O: COVID 19 VIRUS A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 30 mg QD + TCS [redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:83.3 KG								
	BE	113 TO	296	408	R: PAROXYSMAL ATRIAL FIBRILATION S: 心臓障害 P: 心房細動 L: Paroxysmal atrial fibrillation	E: 408 L: 1 Day	T: Grade 2 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Important medical or surgical intervention O: COVID 19 VIRUS A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:MALE RACE:ASIAN WEIGHT:54.3 KG

PRE TO -1

DB 1 TO 112

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV:[redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:2[redacted] SEX:MALE RACE:ASIAN WEIGHT:54.3 KG								
	BE	113 TO	610	722	R: HERPES ZOSTER S: 感染症および寄生虫症 P: 帯状疱疹 L: Herpes zoster	E: 730 L: 9 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY, Prednisolone|NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization A: REASONABLE POSSIBILITY E: No

Note: Treatment-emergent 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: Placebo + TCS/UPA 30 mg QD + TCS

[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:43.0 KG

PRE TO -1

DB 1 TO 112

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 30 mg QD + TCS								
[redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:43.0 KG								
	BE	113 TO	213	325	R: DISSECTION OF THE AORTA S: 血管障害 P: 大動脈解離 L: Aortic dissection	E: 339 L: 15 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, DESONIDE|NO REASONABLE POSSIBILITY, HYDROCORTISONE BUTYRATE|NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: NONE	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: DISSECTION OF AORTA TYPE B. PATIENT HOSPITALIZED IN STRASBOURG (HOPITAL CIVIL) IN VASCULAR SURGERY DEPARTMENT. NO SURGICAL INTERVENTION PLANNED. MORE INFORMATION TO BE REQUESTED. A: NO REASONABLE P

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 30 mg QD + TCS [redacted] AGE:5[redacted] SEX:FEMALE RACE:WHITE WEIGHT:43.0 KG								
	BE	113 TO	309	421	R: PULMONARY NODULE S: 呼吸器、胸郭および縦隔障害 P: 肺腫瘤 L: Lung nodule	E: 423 L: 3 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Desonide|NO REASONABLE POSSIBILITY, Hydrocortisone butyrate|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: BIOPSY OF PULMONARY NODULE	S: Yes, Hospitalization or prolonged hospitalization O: PROCEDURE PLANED UPON CT SCAN DONE ON 14 AUG 2020 A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:52.0 KG

PRE TO -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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS [redacted] AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:52.0 KG								
	DB	1 TO 79	13	13	R: TONSILLAR PHLEGMON INFECTION, THROAT PAIN SINCE ONE DAY S: 感染症および寄生虫症 P: 扁桃周囲膿瘍 L: Peritonsillar abscess	E: 16 L: 4 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Betamethasone valerate|NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: THE CAUSE OF EVENT IS STILL UNKNOWN A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:52.0 KG								
	DB	1 TO 79	13	13	R: TONSILLAR PHLEGMON INFECTION, THROAT PAIN SINCE ONE DAY S: 呼吸器、胸郭および縦隔障害 P: 口腔咽頭痛 L: Throat pain	E: 16 L: 4 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Betamethasone valerate|NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: THE CAUSE OF EVENT IS STILL UNKNOWN A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:52.0 KG								
	DB	1 TO 79	79	79	R: SUICIDE ATTEMPT S: 精神障害 P: 自殺企図 L: Suicide attempt	E: 81 L: 3 Days	T: Grade 4 R: UPADACITINIB/PLACEBO|REASONABLE POSSIBILITY, Betamethasone valerate|NO REASONABLE POSSIBILITY, Fluticasone propionate|NO REASONABLE POSSIBILITY A: STUDY TREATMENT PERMANENTLY DISCONTINUED O: CONCOMITANT MEDICATION OR THERAPY DISCONTINUED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention, Life threatening A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:52.0 KG

FU 80 TO

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:65.0 KG

PRE	TO -1
DB	1 TO 114
BE	115 TO 253

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:65.0 KG								
	FU	254 TO	6	259	R: ELECTIVE ABORTION S: 外科および内科処置 P: 人工流産 L: Elective abortion	E: 269 L: 11 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Betamethasone valerate|NO REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: DISCONTINUED STUDY	S: Yes, Important medical or surgical intervention O: PATIENT DECISION A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: Placebo + TCS/UPA 15 mg QD + TCS

[redacted] AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:59.4 KG

PRE TO -1

DB 1 TO 113

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 15 mg QD + TCS [redacted] AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:59.4 KG								
	BE	114 TO	266	379	R: INFECTIOUS COLITIS S: 感染症および寄生虫症 P: 大腸感染 L: Infectious colitis	E: 384 L: 6 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY, BETAMETHASON DIPROPIONATE|NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, COVID-19 TEST (NE	S: Yes, Important medical or surgical intervention O: REASONABLE POSSIBILITY OF RELATIONSHIP TOWARDS DICLOFENAC (CONCOMITANT MEDICATION) A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: Placebo + TCS/UPA 30 mg QD + TCS

[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:63.6 KG

PRE TO -1

DB 1 TO 112

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 30 mg QD + TCS								
[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:63.6 KG								
	BE	113 TO	341	453	R: INTRA-ARTICULAR DISTAL RADIUS FRACTURE LEFT WRIST S: 傷害、中毒および処置合併症 P: 橈骨骨折 L: Radius fracture		T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY, Mometasone furoate|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, LEFT WRISTE PLATE OST	S: Yes, Hospitalization or prolonged hospitalization O: FALL A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:64.5 KG

PRE TO -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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:64.5 KG								
	DB	1 TO 117	48	48	R: ACUTE APPENDICITIS S: 感染症および寄生虫症 P: 虫垂炎 L: Acute appendicitis	E: 49 L: 2 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY, Betamethasone valerate|NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: LAPAROSCOPIC APPENDECTOMY	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention A: NO REASONABLE POSSIBILITY
	BE	118 TO 194						

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:64.5 KG

FU 195 TO

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: Placebo + TCS/UPA 15 mg QD + TCS

[redacted] AGE:2[redacted] SEX:FEMALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:42.0 KG

PRE	TO -1
DB	1 TO 116
BE	117 TO 304

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 15 mg QD + TCS								
[redacted] AGE:2[redacted] SEX:FEMALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:42.0 KG								
	FU	305 TO	15	319	R: GENERALIZED ANXIETY DISORDER, SEVERE PRURITIS, CHEST PAIN, WEIGHT LOSS S: 一般・全身障害および投与部位の状態 P: 胸痛 L: Chest pain	O: Yes	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Betamethasone valerate|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: AS PER HOSPITAL REPORT, NO CLEAR CAUSE OF CHEST PAIN OR WEIGHT LOSS WAS FOUND. RELEVANT INVESTIGATIONS AND RESULTS HAVE BEEN UPDATED IN THE SAE SUPPLEMENTALS A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 15 mg QD + TCS [redacted] AGE:2[redacted] SEX:FEMALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:42.0 KG								
	FU	305 TO	15	319	R: GENERALIZED ANXIETY DISORDER, SEVERE PRURITIS, CHEST PAIN, WEIGHT LOSS S: 臨床検査 P: 体重減少 L: Weight loss	O: Yes	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Betamethasone valerate|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: AS PER HOSPITAL REPORT, NO CLEAR CAUSE OF CHEST PAIN OR WEIGHT LOSS WAS FOUND. RELEVANT INVESTIGATIONS AND RESULTS HAVE BEEN UPDATED IN THE SAE SUPPLEMENTALS A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 15 mg QD + TCS								
[redacted] AGE:2[redacted] SEX:FEMALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:42.0 KG								
	FU	305 TO	15	319	R: GENERALIZED ANXIETY DISORDER, SEVERE PRURITIS, CHEST PAIN, WEIGHT LOSS S: 精神障害 P: 全般性不安障害 L: Generalized anxiety disorder	O: Yes	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Betamethasone valerate|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: AS PER HOSPITAL REPORT, NO CLEAR CAUSE OF CHEST PAIN OR WEIGHT LOSS WAS FOUND. RELEVANT INVESTIGATIONS AND RESULTS HAVE BEEN UPDATED IN THE SAE SUPPLEMENTALS A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 15 mg QD + TCS								
[redacted] AGE:2[redacted] SEX:FEMALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:42.0 KG								
	FU	305 TO	15	319	R: GENERALIZED ANXIETY DISORDER, SEVERE PRURITIS, CHEST PAIN, WEIGHT LOSS S: 皮膚および皮下組織障害 P: そう痒症 L: Pruritus	O: Yes	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Betamethasone valerate|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: AS PER HOSPITAL REPORT, NO CLEAR CAUSE OF CHEST PAIN OR WEIGHT LOSS WAS FOUND. RELEVANT INVESTIGATIONS AND RESULTS HAVE BEEN UPDATED IN THE SAE SUPPLEMENTALS A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:110.8 KG

PRE TO -1

DB 1 TO 111

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:110.8 KG								
	BE	112 TO 363	208	319	R: SQUAMOUS CELL CARCINOMA BUCCAL MUCOSA S: 良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む） P: 口腔内扁平上皮癌 L: Squamous cell carcinoma of the oral cavity	E: 327 L: 9 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:110.8 KG

FU 364 TO

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:68.0 KG

PRE TO -1

DB 1 TO 105

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:68.0 KG								
	BE	106 TO	267	372	R: HERPES ZOSTER S: 感染症および寄生虫症 P: 帯状疱疹 L: Herpes zoster		T: Grade 3 R: UPADACITINIB/PLACEBO|REASONABLE POSSIBILITY, Betamethasone valerate|NO REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY, Tacrolimus|NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization A: REASONABLE POSSIBILITY E: No

Note: Treatment-emergent 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:100.2 KG

PRE TO -1

DB 1 TO 110

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:100.2 KG								
	BE	111 TO 328	218	328	R: STROKE S: 神経系障害 P: 脳血管発作 L: Stroke	O: Yes	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: NONE	S: Yes, Hospitalization or prolonged hospitalization, Life threatening O: CARDIAC HISTORY INDICATES IT WAS CARDIAC RELATED A: NO REASONABLE POSSIBILITY
	FU	329 TO						

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:89.6 KG

PRE TO -1

DB 1 TO 115

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:89.6 KG								
	BE	116 TO	302	417	R: ACUTE CORONARY SYNDROME (ATYPICAL CHEST PAIN) S: 心臓障害 P: 急性冠動脈症候群 L: Acute coronary syndrome	E: 420 L: 4 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: PAST MEDICAL HISTORY OF CORONARY ARTERY DISEASE WITH 3 STENTS A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:89.6 KG								
	BE	116 TO	302	417	R: ACUTE CORONARY SYNDROME (ATYPICAL CHEST PAIN) S: 一般・全身障害および投与部位の状態 P: 胸痛 L: Chest pain	E: 420 L: 4 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: PAST MEDICAL HISTORY OF CORONARY ARTERY DISEASE WITH 3 STENTS A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS [redacted] AGE:7[redacted] SEX:FEMALE RACE:WHITE WEIGHT:89.6 KG								
	BE	116 TO	501	616	R: COVID-19 INFECTION S: 感染症および寄生虫症 P: コロナウイルス感染 L: Coronavirus infection		T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: COVID-19 POSITIVE	S: Yes, Hospitalization or prolonged hospitalization O: POSSIBLY RELATED TO COPD EXACERBATION

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:1[redacted] SEX:FEMALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:65.3 KG

PRE TO -1

DB 1 TO 112

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:1[redacted] SEX:FEMALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:65.3 KG								
	BE	113 TO	302	414	R: BARTONELLA S: 感染症および寄生虫症 P: バルトネラ症 L: Bartonellosis	I: Yes	T: Grade 3 R: UPADACITINIB/PLACEBO|REASONABLE POSSIBILITY, Triamcinolone acetonide|REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, CONCOMITANT MEDICATION OR THERAPY DISCONTINUED)	S: Yes, Hospitalization or prolonged hospitalization E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:91.5 KG

PRE TO -1

DB 1 TO 112

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:4[redacted] SEX:MALE RACE:WHITE WEIGHT:91.5 KG								
	BE	113 TO	218	330	R: FIFTH METATARSAL FRACTURE S: 傷害、中毒および処置合併症 P: 足骨折 L: Fractured metatarsal		T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY, Mometasone furoate|NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: INJURY/FALL DUE TO PHYSICAL ACTIVITY A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:60.0 KG

PRE TO -1

DB 1 TO 119

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:60.0 KG								
	BE	120 TO 159	36	155	R: DISSEMINATED HERPES ZOSTER S: 感染症および寄生虫症 P: 播種性帯状疱疹 L: Herpes zoster disseminated	E: 174 L: 20 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: Yes, Hospitalization or prolonged hospitalization

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:60.0 KG

FU 160 TO

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:72.8 KG

PRE TO -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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:72.8 KG								
	DB	1 TO 115	37	37	R: STREPTOCOCCUS PHARYNGITIS S: 感染症および寄生虫症 P: レンサ球菌性咽頭炎 L: Streptococcal pharyngitis	E: 45 L: 9 Days	T: Grade 4 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY, Betamethasone valerate|NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: EXPOSURE TO BACTERIA A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:72.8 KG

BE 116 TO

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:87.0 KG

PRE TO -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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:87.0 KG								
	DB	1 TO 104	100	100	R: PLEURAL EFFUSION S: 呼吸器、胸郭および縦隔障害 P: 胸水 L: Pleural effusion	E: 102 L: 3 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY

Note: Treatment-emergent 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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:87.0 KG

FU 105 TO

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:106.6 KG

PRE TO -1

DB 1 TO 115

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:106.6 KG								
	BE	116 TO	232	347	R: AUTOMOBILE ACCIDENT S: 傷害、中毒および処置合併症 P: 交通事故 L: Automobile accident	E: 347 L: 1 Day	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: IN HOSPITAL	S: Yes, Hospitalization or prolonged hospitalization O: FELL ASLEEP AT THE WHEEL A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:106.6 KG								
	BE	116 TO	232	347	R: RIGHT LEG COMPOUND FRACTURE S: 傷害、中毒および処置合併症 P: 開放骨折 L: Compound fracture		T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: DUE TO CAR ACCIDENT A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:84.0 KG

PRE TO -1

DB 1 TO 113

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:84.0 KG								
	BE	114 TO 204	78	191	R: WORSENING OF ATOPIC DERMATITIS S: 皮膚および皮下組織障害 P: アトピー性皮膚炎 L: Dermatitis atopic aggravated	O: Yes	T: Grade 4 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY, Pimecrolimus|NO REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, DISCONTINUED STUDY)	S: Yes, Hospitalization or prolonged hospitalization O: ATOPIC DERMATITIS A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:84.0 KG

FU 205 TO

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:67.8 KG

PRE TO -1

DB 1 TO 113

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:67.8 KG								
	BE	114 TO 208	79	192	R: EXACERBATION ECZEMA S: 皮膚および皮下組織障害 P: 湿疹 L: Eczema exacerbated	E: 241 L: 50 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Betamethasone valerate|NO REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY, Mometasone furoate|NO REASONABLE POSSIBILITY A: STUDY MEDICATION WAS ALREADY WITHDRAWN O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY	S: Yes, Hospitalization or prolonged hospitalization O: WITHDRAWN OF STUDY MEDICATION A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:67.8 KG

FU 209 TO

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:96.5 KG

PRE TO -1

DB 1 TO 114

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:96.5 KG								
	BE	115 TO	295	409	R: BROKEN ANKLE RIGHT S: 傷害、中毒および処置合併症 P: 足関節部骨折 L: Broken ankle	E: 429 L: 21 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Betamethasone valerate|NO REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY, Mometasone furoate|NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Important medical or surgical intervention O: FALL FROM STAIRS, BROKE HIS RIGHT ANKLE, HAD TO UNDERGO SURGERY TO PLACE OSTEOSYNTHESIS MATERIAL A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:92.5 KG

PRE	TO -1
DB	1 TO 112
BE	113 TO 267

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:92.5 KG								
	FU	268 TO	1	268	R: SUBARACHNOID HEMORRHAGE S: 神経系障害 P: くも膜下出血 L: Subarachnoid hemorrhage	E: 274 L: 7 Days	T: Grade 4 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Fluocinolone acetonide|NO REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization, Life threatening O: IDEOPATHIC A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:91.6 KG

PRE TO -1

DB 1 TO 113

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:91.6 KG								
	BE	114 TO	290	403	R: LEFT DISTAL FEMUR FRACTURE S: 傷害、中毒および処置合併症 P: 大腿骨骨折 L: Femur fracture	E: 414 L: 12 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: NONE	S: Yes, Hospitalization or prolonged hospitalization, Persistent or significant disability/incapacity, Important medical or surgical intervention O: [redacted] PT FELL AT HOME AND WAS HOSPITALIZED UNTIL 2/18 & THEN TX TO REHAB [redacted] ADMITTED BACK TO HOSP ON [redacted] FOR SCHEDULED SURGERY AND D/C

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:57.5 KG

PRE TO -1

DB 1 TO 110

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:57.5 KG								
	BE	111 TO 126	16	126	R: FURTHER DECREASE OF HAEMOGLOBIN LEVEL S: 臨床検査 P: ヘモグロビン減少 L: Haemoglobin decreased	O: Yes	T: Grade 3 R: UPADACITINIB/PLACEBO|REASONABLE POSSIBILITY, CLOBETASOL PROPIONATE|NO REASONABLE POSSIBILITY, Mometasone furoate|NO REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: DISCONTINUED STUDY	S: Yes, Hospitalization or prolonged hospitalization A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:57.5 KG

FU 127 TO

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:MALE RACE:ASIAN WEIGHT:48.5 KG

PRE TO -1

DB 1 TO 112

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:2[redacted] SEX:MALE RACE:ASIAN WEIGHT:48.5 KG								
	BE	113 TO	122	234	R: CUTANEOUS GENERALIZED HERPES ZOSTER S: 感染症および寄生虫症 P: 皮膚播種性帯状疱疹 L: Herpes zoster cutaneous disseminated	E: 251 L: 18 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|REASONABLE POSSIBILITY, Prednisolone|NO REASONABLE POSSIBILITY, Fluocinolone acetonide|NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization A: REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: Placebo + TCS/UPA 30 mg QD + TCS

[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:71.8 KG

PRE TO -1

DB 1 TO 108

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 30 mg QD + TCS								
[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:71.8 KG								
	BE	109 TO	187	295	R: PALPITATIONS S: 心臓障害 P: 動悸 L: Palpitations	E: 618 L: 324 Days I: Yes	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Tacrolimus|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, CONCOMITANT MEDICATION OR THERAPY DISCONTINUED)	S: Yes, Hospitalization or prolonged hospitalization O: THERE IS NPO OTHER CAUSE OF EVENT, NO OTHER RISK FACTORS A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 30 mg QD + TCS								
[redacted] AGE:3[redacted] SEX:FEMALE RACE:WHITE WEIGHT:71.8 KG								
	BE	109 TO	298	406	R: PALPITATIONS S: 心臓障害 P: 動悸 L: Palpitations	E: 407 L: 2 Days I: Yes	T: Grade 2 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Tacrolimus|NO REASONABLE POSSIBILITY, Fluticasone propionate|NO REASONABLE POSSIBILITY, Betamethasone valerate|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: PALPITATIONS A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:113.0 KG

PRE TO -1

DB 1 TO 112

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:4[redacted] SEX:FEMALE RACE:WHITE WEIGHT:113.0 KG								
	BE	113 TO	275	387	R: MIGRENE S: 神経系障害 P: 片頭痛 L: Migraine	E: 388 L: 2 Days	T: Grade 1 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Hydrocortisone butyrate|NO REASONABLE POSSIBILITY, Pimecrolimus|NO REASONABLE POSSIBILITY, Fluticasone propionate|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: STRESS AT WORK A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

INV: [redacted] ([redacted])
TRT: Placebo + TCS/UPA 30 mg QD + TCS

[redacted] AGE:3[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:70.6 KG

PRE TO -1

DB 1 TO 188

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: Placebo + TCS/UPA 30 mg QD + TCS [redacted] AGE:3[redacted] SEX:FEMALE RACE:ASIAN WEIGHT:70.6 KG								
	BE	189 TO	89	277	R: SPONTANEOUS ABORTION S: 妊娠、産褥および周産期の状態 P: 自然流産 L: Spontaneous abortion	E: 323 L: 47 Days	T: Grade 2 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Betamethasone valerate|NO REASONABLE POSSIBILITY, Hydrocortisone valerate|NO REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: NONE	S: Yes, Important medical or surgical intervention O: IDIOPATHIC A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:MALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:71.5 KG

PRE TO -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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:2[redacted] SEX:MALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:71.5 KG								
	DB	1 TO 218	93	93	R: ASTHMA ATTACK S: 呼吸器、胸郭および縦隔障害 P: 喘息 L: Asthmatic attack	E: 95 L: 3 Days	T: Grade 4 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Hydrocortisone valerate|NO REASONABLE POSSIBILITY, Betamethasone valerate|NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: ASTHMA ATTACK A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:2[redacted] SEX:MALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:71.5 KG								
	DB	1 TO 218	102	102	R: STATUS ASTHMATICUS S: 呼吸器、胸郭および縦隔障害 P: 喘息発作重積 L: Status asthmaticus	E: 107 L: 6 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Hydrocortisone valerate|NO REASONABLE POSSIBILITY, Betamethasone valerate|NO REASONABLE POSSIBILITY A: STUDY TREATMENT ALREADY ON HOLD O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: EXPOSURE TO ALLERGEN A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:2[redacted] SEX:MALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:71.5 KG								
	BE	219 TO	20	238	R: CLOSED HEAD INJURY S: 傷害、中毒および処置合併症 P: 頭蓋脳損傷 L: Closed head injury	E: 253 L: 16 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Hydrocortisone valerate|NO REASONABLE POSSIBILITY, Betamethasone valerate|NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: TRAUMATIC FALL A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:69.0 KG

PRE TO -1

DB 1 TO 117

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:69.0 KG								
	BE	118 TO	89	206	R: FRACTURED LEFT CLAVICLE S: 傷害、中毒および処置合併症 P: 鎖骨骨折 L: Clavicle fracture	E: 223 L: 18 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Mometasone furoate|NO REASONABLE POSSIBILITY, Hydrocortisone acetate|NO REASONABLE POSSIBILITY, EUMOVATE|NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: MULTIPLE (CONCOMITANT MEDICATION OR THERAPY STARTED, SURGERY)	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: FELL OFF MOUNTAIN BIKE A: NO REASONABLE POSSIBILITY

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:2[redacted] SEX:MALE RACE:WHITE WEIGHT:69.0 KG								
	BE	118 TO	315	432	R: RIGHT SIDED PLEURITIC CHEST PAIN. S: 呼吸器、胸郭および縦隔障害 P: 胸膜痛 L: Pleuritic pain	E: 433 L: 2 Days	T: Grade 1 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Hydrocortisone|NO REASONABLE POSSIBILITY, Mometasone furoate|NO REASONABLE POSSIBILITY, EUMOVATE CLOBETASONE BUTYRATE|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: NONE	S: Yes, Hospitalization or prolonged hospitalization O: PLEURITIC CHEST PAIN.PATIENT JUST FELT UNWELL AND SUFFERED CHEST PAIN. NO SPECIFIC CAUSE. A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:74.0 KG

PRE TO -1

DB 1 TO 114

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 15 mg QD + TCS								
[redacted] AGE:5[redacted] SEX:MALE RACE:WHITE WEIGHT:74.0 KG								
	BE	115 TO	123	237	R: SPONTANOUS PASSAGE OF RENAL STONE S: 腎および尿路障害 P: 尿路結石 L: Spontaneous passage of urinary calculus	E: 238 L: 2 Days	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Mometasone furoate|NO REASONABLE POSSIBILITY, Tacrolimus|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: CONCOMITANT MEDICATION OR THERAPY STARTED	S: Yes, Hospitalization or prolonged hospitalization O: KNOW UROLITHIASIS A: NO REASONABLE POSSIBILITY E: No

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?

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

[redacted] AGE:6[redacted] SEX:MALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:110.9 KG

PRE TO -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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	T: Toxicity Grade R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality E: Event Related to COVID-19 Infection?
INV: [redacted] ([redacted]) TRT: UPA 30 mg QD + TCS								
[redacted] AGE:6[redacted] SEX:MALE RACE:BLACK OR AFRICAN AMERICAN WEIGHT:110.9 KG								
	DB	1 TO 89	77	77	R: WORSENING OF CONGESTIVE HEART FAILURE S: 心臓障害 P: うっ血性心不全 L: Congestive cardiac failure aggravated	O: Yes	T: Grade 3 R: UPADACITINIB/PLACEBO|NO REASONABLE POSSIBILITY, Triamcinolone acetonide|NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: ICD PLACEMENT	S: Yes, Hospitalization or prolonged hospitalization, Important medical or surgical intervention O: PROGRESSION OF DISEASE A: NO REASONABLE POSSIBILITY
	FU	90 TO						

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. Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.
PRE = Screening; DB = Double-blind treatment; BE = Blind extension treatment; FU = Follow-up.
# Subject prematurely discontinued.
被験者番号[redacted], [redacted]及び[redacted]は日本人であった。
相互参照：M16-047 試験 CSR W52 Table 14.3__2.25.1

表 2.7.4.7-41. 全試験期間中（投与 24 週時データカットオフまで）の重篤な有害事象の一覧表（Safety_DB 集団）：M17-377 試験

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: PLACEBO/ABT-494 30 MG QD								
[redacted] Age: 4[redacted] Sex: Female Race: ASIAN Weight: 56.7 KG								
	DB	1 to 112	76	76	R: CHOLECYSTOLITHIASIS S: 肝胆道系障害 P: 胆石症 L: Cholecystolithiasis	E: 200 L: 125 days I: No	S: Moderate R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: LAPAROSCOPIC CHOLECYSTECTOMY	S: Yes O: THE RISK OF ONSET WAS HIGH, INCLUDING AGE AND GENDER. A: NO REASONABLE POSSIBILITY

Note: 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.
PRE = SCREENING; DB = DOUBLE-BLIND TREATMENT; BE = BLINDED EXTENSION TREATMENT; OL = OPEN-LABEL TREATMENT; FU = FOLLOW-UP.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ABT-494 15 MG QD								
[redacted] Age: 2[redacted] Sex: Male Race: ASIAN Weight: 53.0 KG								
	DB	1 to 65	65	65	R: CEREBELLAR HAEMORRHAGE S: 神経系障害 P: 小脳出血 L: Cerebellar haemorrhage	E: 123 L: 59 days I: No	S: Severe R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes A: NO REASONABLE POSSIBILITY

Note: 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.
PRE = SCREENING; DB = DOUBLE-BLIND TREATMENT; BE = BLINDED EXTENSION TREATMENT; OL = OPEN-LABEL TREATMENT; FU = FOLLOW-UP.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: PLACEBO/ABT-494 15 MG QD								
[redacted] Age: 5[redacted] Sex: Male Race: ASIAN Weight: 79.4 KG								
	FU	184 to	5	188	R: PNEUMOCYSTIS PNEUMONIA S: 感染症および寄生虫症 P: ニューモシスチス・イロベチイ肺炎 L: Pneumocystis pneumonia	E: 212 L: 25 days I: No	S: Severe R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes A: REASONABLE POSSIBILITY

Note: 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.

PRE = SCREENING; DB = DOUBLE-BLIND TREATMENT; BE = BLINDED EXTENSION TREATMENT; OL = OPEN-LABEL TREATMENT; FU = FOLLOW-UP.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ABT-494 15 MG QD								
[redacted] Age: 2[redacted] Sex: Male Race: ASIAN Weight: 56.1 KG								
	BE	110 to	145	254	R: HERPES ZOSTER S: 感染症および寄生虫症 P: 帯状疱疹 L: Herpes zoster	E: 265 L: 12 days I: No	S: Severe R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED	S: Yes A: REASONABLE POSSIBILITY

Note: 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.

PRE = SCREENING; DB = DOUBLE-BLIND TREATMENT; BE = BLINDED EXTENSION TREATMENT; OL = OPEN-LABEL TREATMENT; FU = FOLLOW-UP.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: PLACEBO/ABT-494 30 MG QD								
[redacted] Age: 5[redacted] Sex: Male Race: ASIAN Weight: 74.7 KG								
	BE	111 to	156	266	R: HERPES ZOSTER S: 感染症および寄生虫症 P: 帯状疱疹 L: Herpes zoster	E: 286 L: 21 days I: No	S: Severe R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED	S: Yes A: REASONABLE POSSIBILITY

Note: 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.

PRE = SCREENING; DB = DOUBLE-BLIND TREATMENT; BE = BLINDED EXTENSION TREATMENT; OL = OPEN-LABEL TREATMENT; FU = FOLLOW-UP.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ABT-494 30 MG QD								
[redacted] Age: 3[redacted] Sex: Male Race: ASIAN Weight: 56.4 KG								
	DB	1 to 115	34	34	R: HERPES SIMPLEX AGGRAVATED S: 感染症および寄生虫症 P: 単純ヘルペス L: Herpes simplex aggravated	E: 45 L: 12 days I: No	S: Severe R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED	S: Yes A: REASONABLE POSSIBILITY

Note: 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.
PRE = SCREENING; DB = DOUBLE-BLIND TREATMENT; BE = BLINDED EXTENSION TREATMENT; OL = OPEN-LABEL TREATMENT; FU = FOLLOW-UP.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ABT-494 30 MG QD								
[redacted] Age: 4[redacted] Sex: Male Race: ASIAN Weight: 71.0 KG								
	BE	111 to 362	121	231	R: HERPES ZOSTER S: 感染症および寄生虫症 P: 帯状疱疹 L: Herpes zoster	E: 315 L: 85 days I: No	S: Severe R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes A: REASONABLE POSSIBILITY

Note: 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.

PRE = SCREENING; DB = DOUBLE-BLIND TREATMENT; BE = BLINDED EXTENSION TREATMENT; OL = OPEN-LABEL TREATMENT; FU = FOLLOW-UP.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: PLACEBO/ABT-494 15 MG QD								
[redacted] Age: 4[redacted] Sex: Male Race: ASIAN Weight: 87.0 KG								
	BE	110 to	151	260	R: SUBMANDIBULAR CELLULITIS IN THE LEFT S: 感染症および寄生虫症 P: 蜂巣炎 L: Cellulitis	I: No	S: Severe R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes O: NO REASONABLE POSSIBILITY WITH STUDY DRUG BECAUSE IT IS CAUSED BY INFLAMED TEETH. A: NO REASONABLE POSSIBILITY

Note: 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.
PRE = SCREENING; DB = DOUBLE-BLIND TREATMENT; BE = BLINDED EXTENSION TREATMENT; OL = OPEN-LABEL TREATMENT; FU = FOLLOW-UP.

いずれの症例（被験者番号[redacted], [redacted], [redacted], [redacted], [redacted], [redacted], [redacted] 及び [redacted]）も日本人であった。

相互参照：M17-377 試験 CSR W24 Table 14.3　2.23.1

表 2.7.4.7-42. 全試験期間中（投与 52 週時データカットオフまで）の重篤な有害事象の一覧表（Safety_DB 集団）：M17-377 試験

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: PLACEBO/ABT-494 30 MG QD								
[redacted] Age: 4[redacted] Sex: Female Race: ASIAN Weight: 56.7 KG								
	DB	1 to 112	76	76	R: CHOLECYSTOLITHIASIS S: 肝胆道系障害 P: 胆石症 L: Cholecystolithiasis	E: 200 L: 125 days I: No	S: Moderate R: NO REASONABLE POSSIBILITY A: DRUG INTERRUPTED O: LAPAROSCOPIC CHOLECYSTECTOMY	S: Yes O: THE RISK OF ONSET WAS HIGH, INCLUDING AGE AND GENDER. A: NO REASONABLE POSSIBILITY

Note: 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.
PRE = SCREENING; DB = DOUBLE-BLIND TREATMENT; BE = BLINDED EXTENSION TREATMENT; OL = OPEN-LABEL TREATMENT; FU = FOLLOW-UP.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: PLACEBO/ABT-494 30 MG QD								
[redacted] Age: 3[redacted] Sex: Male Race: ASIAN Weight: 72.9 KG								
	BE	110 to 357	74	183	R: APPENDICITIS S: 感染症および寄生虫症 P: 虫垂炎 L: Appendicitis	E: 278 L: 96 days I: No	S: Severe R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED	S: Yes A: NO REASONABLE POSSIBILITY
	OL	358 to	1	358	R: PNEUMOTHORAX S: 呼吸器、胸郭および縦隔障害 P: 気胸 L: Pneumothorax	I: No	S: Severe R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED	S: Yes A: NO REASONABLE POSSIBILITY

Note: 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.
PRE = SCREENING; DB = DOUBLE-BLIND TREATMENT; BE = BLINDED EXTENSION TREATMENT; OL = OPEN-LABEL TREATMENT; FU = FOLLOW-UP.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ABT-494 15 MG QD								
[redacted] Age: 2[redacted] Sex: Male Race: ASIAN Weight: 53.0 KG								
	DB	1 to 65	65	65	R: CEREBELLAR HAEMORRHAGE S: 神経系障害 P: 小脳出血 L: Cerebellar haemorrhage	E: 123 L: 59 days I: No	S: Severe R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes A: NO REASONABLE POSSIBILITY

Note: 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.

PRE = SCREENING; DB = DOUBLE-BLIND TREATMENT; BE = BLINDED EXTENSION TREATMENT; OL = OPEN-LABEL TREATMENT; FU = FOLLOW-UP.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: PLACEBO/ABT-494 15 MG QD								
[redacted] Age: 5[redacted] Sex: Male Race: ASIAN Weight: 79.4 KG								
	FU	184 to	5	188	R: PNEUMOCYSTIS PNEUMONIA S: 感染症および寄生虫症 P: ニューモシスチス・イロベチイ肺炎 L: Pneumocystis pneumonia	E: 212 L: 25 days I: No	S: Severe R: REASONABLE POSSIBILITY A: DRUG WITHDRAWN	S: Yes A: REASONABLE POSSIBILITY

Note: 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.

PRE = SCREENING; DB = DOUBLE-BLIND TREATMENT; BE = BLINDED EXTENSION TREATMENT; OL = OPEN-LABEL TREATMENT; FU = FOLLOW-UP.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ABT-494 15 MG QD								
[redacted] Age: 5[redacted] Sex: Male Race: ASIAN Weight: 78.4 KG								
	BE	114 to 358	36	149	R: WORSENING OF TYPE 2 DIABETIC CATARACT S: 眼障害 P: 糖尿病性白内障 L: Diabetic cataract	E: 225 L: 77 days I: No	S: Severe R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED O: PHACOEMULSIFICATION AND INTRA OCULAR LENS IMPLANTATION.	S: Yes O: IT IS CONSIDERED TO BE WORSENING OF TYPE 2 DIABETIC CATARACT OF COMPLICATIONS. A: NO REASONABLE POSSIBILITY

Note: 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.

PRE = SCREENING; DB = DOUBLE-BLIND TREATMENT; BE = BLINDED EXTENSION TREATMENT; OL = OPEN-LABEL TREATMENT; FU = FOLLOW-UP.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ABT-494 15 MG QD								
[redacted] Age: 2[redacted] Sex: Male Race: ASIAN Weight: 56.1 KG								
	BE	110 to 368	145	254	R: HERPES ZOSTER S: 感染症および寄生虫症 P: 帯状疱疹 L: Herpes zoster	E: 265 L: 12 days I: No	S: Severe R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED	S: Yes A: REASONABLE POSSIBILITY

Note: 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.

PRE = SCREENING; DB = DOUBLE-BLIND TREATMENT; BE = BLINDED EXTENSION TREATMENT; OL = OPEN-LABEL TREATMENT; FU = FOLLOW-UP.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: PLACEBO/ABT-494 30 MG QD								
[redacted] Age: 5[redacted] Sex: Male Race: ASIAN Weight: 74.7 KG								
	BE	111 to 369	156	266	R: HERPES ZOSTER S: 感染症および寄生虫症 P: 帯状疱疹 L: Herpes zoster	E: 286 L: 21 days I: No	S: Severe R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED	S: Yes A: REASONABLE POSSIBILITY

Note: 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.

PRE = SCREENING; DB = DOUBLE-BLIND TREATMENT; BE = BLINDED EXTENSION TREATMENT; OL = OPEN-LABEL TREATMENT; FU = FOLLOW-UP.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ABT-494 30 MG QD								
[redacted] Age: 3[redacted] Sex: Male Race: ASIAN Weight: 56.4 KG								
	DB	1 to 115	34	34	R: HERPES SIMPLEX AGGRAVATED S: 感染症および寄生虫症 P: 単純ヘルペス L: Herpes simplex aggravated	E: 45 L: 12 days I: No	S: Severe R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED	S: Yes A: REASONABLE POSSIBILITY

Note: 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.

PRE = SCREENING; DB = DOUBLE-BLIND TREATMENT; BE = BLINDED EXTENSION TREATMENT; OL = OPEN-LABEL TREATMENT; FU = FOLLOW-UP.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ABT-494 30 MG QD								
[redacted] Age: 4[redacted] Sex: Male Race: ASIAN Weight: 71.0 KG								
	BE	111 to 362	121	231	R: HERPES ZOSTER S: 感染症および寄生虫症 P: 帯状疱疹 L: Herpes zoster	E: 315 L: 85 days I: No	S: Severe R: REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes A: REASONABLE POSSIBILITY

Note: 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.

PRE = SCREENING; DB = DOUBLE-BLIND TREATMENT; BE = BLINDED EXTENSION TREATMENT; OL = OPEN-LABEL TREATMENT; FU = FOLLOW-UP.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: PLACEBO/ABT-494 15 MG QD								
[redacted] Age: 4[redacted] Sex: Male Race: ASIAN Weight: 87.0 KG								
	BE	110 to 368	151	260	R: SUBMANDIBULAR CELLULITIS IN THE LEFT S: 感染症および寄生虫症 P: 蜂巣炎 L: Cellulitis	E: 313 L: 54 days I: No	S: Severe R: NO REASONABLE POSSIBILITY A: DOSE NOT CHANGED	S: Yes O: NO REASONABLE POSSIBILITY WITH STUDY DRUG BECAUSE IT IS CAUSED BY INFLAMED TEETH. A: NO REASONABLE POSSIBILITY

Note: 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.
PRE = SCREENING; DB = DOUBLE-BLIND TREATMENT; BE = BLINDED EXTENSION TREATMENT; OL = OPEN-LABEL TREATMENT; FU = FOLLOW-UP.

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serious AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ABT-494 15 MG QD								
[redacted] Age: 1[redacted] Sex: Male Race: ASIAN Weight: 46.2 KG								
	BE	111 to 360	191	301	R: APPENDICITIS S: 感染症および寄生虫症 P: 虫垂炎 L: Appendicitis	I: No	S: Severe R: REASONABLE POSSIBILITY A: DRUG INTERRUPTED	S: Yes A: NO REASONABLE POSSIBILITY

Note: 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.

PRE = SCREENING; DB = DOUBLE-BLIND TREATMENT; BE = BLINDED EXTENSION TREATMENT; OL = OPEN-LABEL TREATMENT; FU = FOLLOW-UP.

相互参照：M17-377 試験 CSR W52 Table 14.3　2.23.1

表 2.7.4.7-43. 全試験期間中の重篤な有害事象の一覧表（Safety 1 集団）：M16-048 試験

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset/ Switch	R: Reported Term S: System Organ Class P: MedDRA 21.1 Preferred Term L: Lower Level Term	E: RX Day ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serous AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ABT-494 15 MG QD/PLACEBO [redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:84.0 KG								
	P1	1 TO 112	36	36	R:ACUTE APPENDICITIS S: 感染症および寄生虫症 P: 虫垂炎 L:ACUTE APPENDICITIS	E:44 L:9 DAYS I:NO	S:SEVERE R:NO REASONABLE POSSIBILITY A:DRUG INTERRUPTED	S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:IDIOPATHIC A:NO REASONABLE POSSIBILITY
	P2R	135 TO 616	287	421	R:SUPERIOR CUFF TEAR WITH PSEUDOPARALYSIS S: 筋骨格系および結合組織障害 P: 肩回旋筋腱板症候群 L:ROTATOR CUFF TEAR	E:506 L:86 DAYS I:NO	S:MODERATE R:NO REASONABLE POSSIBILITY A:DRUG INTERRUPTED O:NONE	S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:PHYSICAL INJURY A:NO REASONABLE POSSIBILITY

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset/ Switch	R: Reported Term S: System Organ Class P: MedDRA 21.1 Preferred Term L: Lower Level Term	E: RX Day ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serous AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: PLACEBO/ABT-494 30 MG QD [redacted] AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:105.2 KG								
	P1	1 TO 111	45	45	R:ATRIAL FIBRILLATION S: 心臓障害 P: 心房細動 L:ATRIAL FIBRILLATION	E:332 L:288 DAYS I:NO	S:SEVERE R:REASONABLE POSSIBILITY A:DOSE NOT CHANGED	S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION, LIFE THREATENING O:PRE-EXSISTING CONDITION A:NO REASONABLE POSSIBILITY

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset/ Switch	R: Reported Term S: System Organ Class P: MedDRA 21.1 Preferred Term L: Lower Level Term	E: RX Day ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serous AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: PLACEBO/ABT-494 30 MG QD [redacted] AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:105.2 KG								
(CONT.)	P2	112 TO 195	83	194	R:ESOPHAGEAL FISTULA, SEPSIS, PERICARDITIS S: 胃腸障害 P: 食道瘻 L:ESOPHAGEAL FISTULA	E:332 L:139 DAYS	S:SEVERE R:REASONABLE POSSIBILITY A:DRUG WITHDRAWN O:DISCONTINUED STUDY	S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION, LIFE THREATENING, DEATH OF SUBJECT O:ESOPHAGEAL PERFORATION SECONDARY TO ROUTINE SCHEDULED CARDIAC ABLATION RESULTING IN SEPSIS, PERICARDITIS, PLEURAL EFFUSION, AND RENAL FAILURE A:NO REASONABLE POSSIBILITY
				194	S: 心臓障害 P: 心膜炎 L:PERICARDITIS	---------- S A M E A S A B O V E ----------		

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset/ Switch	R: Reported Term S: System Organ Class P: MedDRA 21.1 Preferred Term L: Lower Level Term	E: RX Day ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serous AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: PLACEBO/ABT-494 30 MG QD [redacted] AGE:7[redacted] SEX:MALE RACE:WHITE WEIGHT:105.2 KG								
(CONT.)	P2	112 TO 195	83	194	S: 感染症および寄生虫症 P: 敗血症 L:SEPSIS		---------- S A M E A S A B O V E ----------	
INV: [redacted] ([redacted]) TRT: ABT-494 7.5 MG QD/PLACEBO [redacted] AGE:3[redacted] SEX:MALE RACE:ASIAN WEIGHT:88.8 KG								
	P1	1 TO 111	108	108	R:LEFT LOWER JAW PERICORONITIS S: 感染症および寄生虫症 P: 歯冠周囲炎 L:PERICORONITIS	E:154 L:47 DAYS I:NO	S:MODERATE R:NO REASONABLE POSSIBILITY A:DOSE NOT CHANGED O:NONE	S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:BECAUSE THE PATIENT HAD REPEATED EPISODES OF THE SAME SYMPTOMS BEOFRE THIS CLINICAL TRAIAL. A:NO REASONABLE POSSIBILITY

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset/ Switch	R: Reported Term S: System Organ Class P: MedDRA 21.1 Preferred Term L: Lower Level Term	E: RX Day ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serous AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: ABT-494 30 MG QD/PLACEBO [redacted] AGE:6[redacted] SEX:MALE RACE:WHITE WEIGHT:80.0 KG								
	POST	180 TO	14	193	R:OSTEOARTHRITIS RIGHT HIP S: 筋骨格系および結合組織障害 P: 変形性関節症 L:HIPS OSTEOARTHRITIS	E:197 L:5 DAYS I:NO	S:SEVERE R:NO REASONABLE POSSIBILITY A:DRUG INTERRUPTED	S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:WORSENING OF OSTEOARTHRITIS A:NO REASONABLE POSSIBILITY
INV: [redacted] ([redacted]) TRT: ABT-494 15 MG QD/ABT-494 15 MG QD [redacted] AGE:4[redacted] SEX:MALE RACE:ASIAN WEIGHT:80.6 KG								
	P2R	137 TO 620	329	465	R:URETER STONE S: 腎および尿路障害 P: 尿管結石症 L:URETERAL CALCULUS	E:481 L:17 DAYS I:NO	S:SEVERE R:NO REASONABLE POSSIBILITY A:DOSE NOT CHANGED O:EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY	S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:DEPENDING ON THE BODY CONSTITUTION OF THE SUBJECT A:NO REASONABLE POSSIBILITY

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset/ Switch	R: Reported Term S: System Organ Class P: MedDRA 21.1 Preferred Term L: Lower Level Term	E: RX Day ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serous AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted])								
TRT: ABT-494 7.5 MG QD								
[redacted] AGE:2[redacted] SEX:FEMALE RACE:WHITE WEIGHT:67.0 KG								
	P1	1 TO 17	13	13	R:SKIN INFECTION EXACERBATION ATOPIC DERMATITIS S: 皮膚および皮下組織障害 P: アトピー性皮膚炎 L:DERMATITIS ATOPIC AGGRAVATED	E:21 L:9 DAYS I:NO	S:MODERATE R:NO REASONABLE POSSIBILITY A:DRUG WITHDRAWN O:DISCONTINUED STUDY	S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:CONTACT DERMATITIS A:REASONABLE POSSIBILITY
				13	S: 感染症および寄生虫症 P: 皮膚感染 L:SKIN INFECTION	---------- S A M E A S A B O V E ----------		
TRT: ABT-494 30 MG QD/PLACEBO								
[redacted] AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:112.5 KG								
	P2R	137 TO 523	327	463	R:PULMONARY EMBOLI S: 呼吸器，胸郭および縦隔障害 P: 肺塞栓症 L:PULMONARY EMBOLISM	O:YES I:NO	S:SEVERE R:NO REASONABLE POSSIBILITY A:DRUG INTERRUPTED	S:YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION O:UNKNOWN A:NO REASONABLE POSSIBILITY

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset/ Switch	R: Reported Term S: System Organ Class P: MedDRA 21.1 Preferred Term L: Lower Level Term	E: RX Day ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serous AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: PLACEBO/ABT-494 30 MG QD [redacted] AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:63.4 KG								
	P2	115 TO 539	166	280	R:SQUAMOUS CELL CARCINOMA / RIGHT CLAVICLE, 8 CM FROM STERNAL NOTCH S: 良性，悪性および詳細不明の新生物（嚢胞およびポリープを含む） P: 皮膚有棘細胞癌 L:SQUAMOUS CELL CARCINOMA OF SKIN	O:YES I:NO	S:MILD R:NO REASONABLE POSSIBILITY A:DOSE NOT CHANGED O:EXCISION TO FOLLOW	S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:SUN DAMAGE A:NO REASONABLE POSSIBILITY
				280	R:SQUAMOUS CELL CARCINOMA / RIGHT CLAVICLE, 12 CM FROM STERNAL NOTCH S: 良性，悪性および詳細不明の新生物（嚢胞およびポリープを含む） P: 皮膚有棘細胞癌 L:SQUAMOUS CELL CARCINOMA OF SKIN	O:YES I:NO	S:MILD R:NO REASONABLE POSSIBILITY A:DOSE NOT CHANGED O:EXCISION TO FOLLOW	S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:SUN DAMAGE A:NO REASONABLE POSSIBILITY

Subject Number	------ Name	Epoch Interval	---- Day	RX Day of Onset/ Switch	R: Reported Term S: System Organ Class P: MedDRA 21.1 Preferred Term L: Lower Level Term	E: RX Day ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity R: Relationship to Study Treatment A: Action Taken with Study Treatment O: Other Actions Taken	S: Serous AE? O: Other Cause of Event A: Abbvie Opinion of Causality
INV: [redacted] ([redacted]) TRT: PLACEBO/ABT-494 30 MG QD [redacted] AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:63.4 KG								
(CONT.)	P2	115 TO 539	166	280	R:SQUAMOUS CELL CARCINOMA (DIGITATED)/ RIGHT CHEST, 9 CM FROM STERNAL AREA S: 良性，悪性および詳細不明の新生物（嚢胞およびポリープを含む） P: 皮膚有棘細胞癌 L:SQUAMOUS CELL CARCINOMA OF SKIN	O:YES I:NO	S:MILD R:NO REASONABLE POSSIBILITY A:DOSE NOT CHANGED O:EXCISED ON 14NOV2017	S:YES, IMPORTANT MEDICAL OR SURGICAL INTERVENTION O:SUN DAMAGE A:NO REASONABLE POSSIBILITY
TRT: ABT-494 30 MG QD/PLACEBO [redacted] AGE:6[redacted] SEX:FEMALE RACE:WHITE WEIGHT:76.4 KG								
	POST	392 TO	2	393	R:CARDIOPULMONARY ARREST S: 心臓障害 P: 心肺停止 L:CARDIOPULMONARY ARREST	E:393 L:1 DAY I:NO	S:SEVERE R:REASONABLE POSSIBILITY O:SUBJECT IS DECEASED	S:YES, LIFE THREATENING, DEATH OF SUBJECT A:NO REASONABLE POSSIBILITY

P1 = PERIOD 1 TREATMENT; P2 = PERIOD 2 TREATMENT; P2R = PERIOD 2 AFTER INITIATING THE RESCUE TREATMENT WITH UPA 30 MG; POST = POST STUDY DRUG.
# SUBJECT PREMATURELY DISCONTINUED.
被験者番号[redacted]及び[redacted]は日本人であった。
相互参照：M16-048 試験 CSR Table 14.3　2.17.2

表 2.7.4.7-44. Part 1 期間中の重篤な有害事象の一覧表（安全性解析対象集団，Part 1）：M20-017 試験

Subject Number	------ Name	Epoch Interval	---- Day	RX Day/ Time of Onset@	R: Reported Term S: System Organ Class P: MedDRA 22.1 Preferred Term L: Lower Level Term	E: RX Day/Time Ended O: Ongoing at the End of Study L: Length I: Intermittent?	S: Severity T: Toxicity Grade Relationship To R1: Upadacitinib ER17Y R2: Upadacitinib ER17 A: Action Taken with Study Treatment O: Other Actions Taken C: Concomitant Medication or Therapy Started?	S: Serous AE? O: Other Cause of Event
INV: [redacted] ([redacted]) SEQ: REGIMEN C IN PERIOD 1, REGIMEN A IN PERIOD 2, REGIMEN D IN PERIOD 3, REGIMEN B IN PERIOD 4 (SEQUENCE GROUP 3: CADB) [redacted] AGE:3[redacted] SEX:MALE RACE:WHITE WEIGHT:87.70 KG								
	OFF	10 TO	10	10 19:00 [129:33]	R: CHOLELITHIASIS S: 肝胆道系障害 P: 胆石症 L: CHOLELITHIASIS	E: 12 / 13:00 L: 3 DAYS I: SINGLE EVENT	S: SEVERE T: GRADE 4 R1: NO REASONABLE POSSIBILITY R2: NO REASONABLE POSSIBILITY A: DRUG WITHDRAWN O: HOSPITAL ADMISSION AND CHOLECYSTECTOMY C: YES	S: YES, HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION

Regimen A: Single 15 mg dose of Upadacitinib phase 3 formulation (ER17Y) administered under fasting conditions (Reference for B).
Regimen B: Single 15 mg dose of Upadacitinib market-image formulation (ER17) administered under fasting conditions (Test for A).
Regimen C: Single 15 mg dose of Upadacitinib phase 3 formulation (ER17Y) administered after high-fat/high-calorie meal (Reference for D).
Regimen D: Single 15 mg dose of Upadacitinib market-image formulation (ER17) administered after high-fat/high-calorie meal (Test for C).
@ Time relative to most recent dose in [].
# Subject Prematurely Discontinued.

相互参照：M20-017 試験 CSR Table 14.3 2.1.1

表 2.7.4.7-45. プラセボ対照併合解析集団（16 週，M16-045 試験，M16-047 試験，M17-377 試験，M16-048 試験及び M18-891 試験）の治験薬の投与中止に至った有害事象（全体集団及び日本人集団）

MedDRA 22.1 System Organ Class Preferred Term	Japan Placebo (N=124) n (%)	Japan Active UPA 15 mg QD (N=125) n (%)	Japan Active UPA 30 mg QD (N=127) n (%)	Overall Placebo (N=992) n (%)	Overall Active UPA 15 mg QD (N=990) n (%)	Overall Active UPA 30 mg QD (N=997) n (%)
Any adverse event	6 (4.8)	2 (1.6)	2 (1.6)	35 (3.5)	23 (2.3)	27 (2.7)
血液およびリンパ系障害	0	0	0	0	0	2 (0.2)
好中球減少症	0	0	0	0	0	2 (0.2)
胃腸障害	0	0	0	0	1 (0.1)	3 (0.3)
上腹部痛	0	0	0	0	1 (0.1)	0
鼓腸	0	0	0	0	0	1 (0.1)
胃食道逆流性疾患	0	0	0	0	0	1 (0.1)
悪心	0	0	0	0	0	1 (0.1)
一般・全身障害および投与部位の状態	0	0	2 (1.6)	0	0	5 (0.5)
顔面浮腫	0	0	1 (0.8)	0	0	2 (0.2)
びくびく感	0	0	0	0	0	1 (0.1)
末梢性浮腫	0	0	1 (0.8)	0	0	1 (0.1)
疼痛	0	0	0	0	0	1 (0.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or up to 30 days after the last dose of study drug in DB Period, whichever occurs first.
Subjects are counted once in each row, regardless of the number of events they may have had.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total.
A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

MedDRA 22.1 System Organ Class Preferred Term	Japan Placebo (N=124) n (%)	Japan Active UPA 15 mg QD (N=125) n (%)	Japan Active UPA 30 mg QD (N=127) n (%)	Overall Placebo (N=992) n (%)	Overall Active UPA 15 mg QD (N=990) n (%)	Overall Active UPA 30 mg QD (N=997) n (%)
肝胆道系障害	0	0	0	0	1 (0.1)	0
肝機能異常	0	0	0	0	1 (0.1)	0
免疫系障害	0	0	0	2 (0.2)	0	0
薬物過敏症	0	0	0	2 (0.2)	0	0
感染症および寄生虫症	1 (0.8)	1 (0.8)	0	4 (0.4)	4 (0.4)	5 (0.5)
ブドウ球菌感染性滑液包炎	0	0	0	0	0	1 (0.1)
蜂巣炎	0	0	0	1 (0.1)	0	0
心内膜炎	1 (0.8)	0	0	1 (0.1)	0	0
眼感染	0	0	0	0	1 (0.1)	0
胃腸炎	0	0	0	1 (0.1)	0	0
ヘルペス眼感染	0	0	0	0	1 (0.1)	1 (0.1)
膿痂疹	0	0	0	0	0	1 (0.1)
カポジ水痘様発疹	0	1 (0.8)	0	0	1 (0.1)	0
精巣炎	0	0	0	0	0	1 (0.1)
咽頭膿瘍	0	0	0	0	0	1 (0.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or up to 30 days after the last dose of study drug in DB Period, whichever occurs first.
Subjects are counted once in each row, regardless of the number of events they may have had.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total.
A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

MedDRA 22.1 System Organ Class Preferred Term	Japan Placebo (N=124) n (%)	Japan Active UPA 15 mg QD (N=125) n (%)	Japan Active UPA 30 mg QD (N=127) n (%)	Overall Placebo (N=992) n (%)	Overall Active UPA 15 mg QD (N=990) n (%)	Overall Active UPA 30 mg QD (N=997) n (%)
感染症および寄生虫症 (Cont.)						
肺炎	0	0	0	1 (0.1)	0	0
副鼻腔炎	0	0	0	0	1 (0.1)	0
ブドウ球菌性敗血症	0	0	0	1 (0.1)	0	0
臨床検査	0	0	0	2 (0.2)	1 (0.1)	1 (0.1)
血中クレアチンホスホキナーゼ増加	0	0	0	1 (0.1)	1 (0.1)	0
ヘモグロビン減少	0	0	0	0	0	1 (0.1)
体重増加	0	0	0	1 (0.1)	0	0
代謝および栄養障害	0	0	0	1 (0.1)	0	1 (0.1)
食欲減退	0	0	0	0	0	1 (0.1)
低ナトリウム血症	0	0	0	1 (0.1)	0	0
筋骨格系および結合組織障害	0	0	0	1 (0.1)	1 (0.1)	0
ミオパチー	0	0	0	1 (0.1)	0	0
横紋筋融解症	0	0	0	0	1 (0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or up to 30 days after the last dose of study drug in DB Period, whichever occurs first.
Subjects are counted once in each row, regardless of the number of events they may have had.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total.
A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

MedDRA 22.1 System Organ Class Preferred Term	Japan Placebo (N=124) n (%)	Japan Active UPA 15 mg QD (N=125) n (%)	Japan Active UPA 30 mg QD (N=127) n (%)	Overall Placebo (N=992) n (%)	Overall Active UPA 15 mg QD (N=990) n (%)	Overall Active UPA 30 mg QD (N=997) 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	0	0	0	0	4 (0.4)
結腸腺癌	0	0	0	0	0	1 (0.1)
肛門扁平上皮癌	0	0	0	0	0	1 (0.1)
胃癌	0	0	0	0	0	1 (0.1)
浸潤性乳管癌	0	0	0	0	0	1 (0.1)
神経系障害	0	1 (0.8)	0	1 (0.1)	2 (0.2)	1 (0.1)
小脳出血	0	1 (0.8)	0	0	1 (0.1)	0
注意力障害	0	0	0	0	1 (0.1)	0
浮動性めまい	0	0	0	0	1 (0.1)	0
頭痛	0	0	0	0	1 (0.1)	1 (0.1)
片頭痛	0	0	0	1 (0.1)	0	0
精神障害	0	0	0	1 (0.1)	1 (0.1)	2 (0.2)
不安	0	0	0	1 (0.1)	1 (0.1)	0
双極性障害	0	0	0	0	0	1 (0.1)
混合性不安抑うつ障害	0	0	0	0	0	1 (0.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or up to 30 days after the last dose of study drug in DB Period, whichever occurs first.
Subjects are counted once in each row, regardless of the number of events they may have had.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total.
A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

MedDRA 22.1 System Organ Class Preferred Term	Japan Placebo (N=124) n (%)	Japan Active UPA 15 mg QD (N=125) n (%)	Japan Active UPA 30 mg QD (N=127) n (%)	Overall Placebo (N=992) n (%)	Overall Active UPA 15 mg QD (N=990) n (%)	Overall Active UPA 30 mg QD (N=997) n (%)
精神障害 (Cont.)						
自殺企図	0	0	0	0	0	1 (0.1)
生殖系および乳房障害	0	0	0	1 (0.1)	0	0
生殖器病変	0	0	0	1 (0.1)	0	0
呼吸器、胸郭および縦隔障害	0	0	0	2 (0.2)	1 (0.1)	0
急性呼吸不全	0	0	0	1 (0.1)	0	0
喘息	0	0	0	0	1 (0.1)	0
肺塞栓症	0	0	0	1 (0.1)	0	0
皮膚および皮下組織障害	5 (4.0)	0	1 (0.8)	21 (2.1)	11 (1.1)	7 (0.7)
ざ瘡	0	0	0	0	1 (0.1)	1 (0.1)
アトピー性皮膚炎	4 (3.2)	0	0	16 (1.6)	7 (0.7)	3 (0.3)
全身性剥脱性皮膚炎	0	0	0	2 (0.2)	0	0
湿疹	0	0	0	2 (0.2)	0	1 (0.1)
紅斑	1 (0.8)	0	1 (0.8)	1 (0.1)	0	1 (0.1)
類乾癬	0	0	0	0	0	1 (0.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or up to 30 days after the last dose of study drug in DB Period, whichever occurs first.
Subjects are counted once in each row, regardless of the number of events they may have had.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total.
A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

MedDRA 22.1 System Organ Class Preferred Term	Japan Placebo (N=124) n (%)	Japan Active UPA 15 mg QD (N=125) n (%)	Japan Active UPA 30 mg QD (N=127) n (%)	Overall Placebo (N=992) n (%)	Overall Active UPA 15 mg QD (N=990) n (%)	Overall Active UPA 30 mg QD (N=997) n (%)
皮膚および皮下組織障害 (Cont.)						
そう痒症	0	0	0	0	1 (0.1)	0
斑状丘疹状皮疹	0	0	0	0	1 (0.1)	0
蕁麻疹	0	0	0	0	1 (0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or up to 30 days after the last dose of study drug in DB Period, whichever occurs first.
Subjects are counted once in each row, regardless of the number of events they may have had.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total.
A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

相互参照：ISS Table 2.4　1.3.5

表 2.7.4.7-46. プラセボ対照併合解析集団（16 週，M16-045 試験，M16-047 試験，M17-377 試験，M16-048 試験及び M18-891 試験）の青少年被験者及び成人被験者の治験薬の投与中止に至った有害事象（全体集団及び日本人集団）

Subgroup: Adolescent

MedDRA 22.1 System Organ Class Preferred Term	Japan Placebo (N=10) n (%)	Japan Active UPA 15 mg QD (N=11) n (%)	Japan Active UPA 30 mg QD (N=12) n (%)	Overall Placebo (N=124) n (%)	Overall Active UPA 15 mg QD (N=124) n (%)	Overall Active UPA 30 mg QD (N=124) n (%)
Any adverse event	0	0	0	3 (2.4)	3 (2.4)	0
肝胆道系障害	0	0	0	0	1 (0.8)	0
肝機能異常	0	0	0	0	1 (0.8)	0
免疫系障害	0	0	0	1 (0.8)	0	0
薬物過敏症	0	0	0	1 (0.8)	0	0
呼吸器、胸郭および縦隔障害	0	0	0	0	1 (0.8)	0
喘息	0	0	0	0	1 (0.8)	0
皮膚および皮下組織障害	0	0	0	2 (1.6)	1 (0.8)	0
アトピー性皮膚炎	0	0	0	2 (1.6)	0	0
そう痒症	0	0	0	0	1 (0.8)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or up to 30 days after the last dose of study drug in DB Period, whichever occurs first.
Subjects are counted once in each row, regardless of the number of events they may have had.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total.
A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

Subgroup: Adult

MedDRA 22.1 System Organ Class Preferred Term	Japan Placebo (N=114) n (%)	Japan Active UPA 15 mg QD (N=114) n (%)	Japan Active UPA 30 mg QD (N=115) n (%)	Overall Placebo (N=868) n (%)	Overall Active UPA 15 mg QD (N=866) n (%)	Overall Active UPA 30 mg QD (N=873) n (%)
Any adverse event	6 (5.3)	2 (1.8)	2 (1.7)	32 (3.7)	20 (2.3)	27 (3.1)
血液およびリンパ系障害	0	0	0	0	0	2 (0.2)
好中球減少症	0	0	0	0	0	2 (0.2)
胃腸障害	0	0	0	0	1 (0.1)	3 (0.3)
上腹部痛	0	0	0	0	1 (0.1)	0
鼓腸	0	0	0	0	0	1 (0.1)
胃食道逆流性疾患	0	0	0	0	0	1 (0.1)
悪心	0	0	0	0	0	1 (0.1)
一般・全身障害および投与部位の状態	0	0	2 (1.7)	0	0	5 (0.6)
顔面浮腫	0	0	1 (0.9)	0	0	2 (0.2)
びくびく感	0	0	0	0	0	1 (0.1)
末梢性浮腫	0	0	1 (0.9)	0	0	1 (0.1)
疼痛	0	0	0	0	0	1 (0.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or up to 30 days after the last dose of study drug in DB Period, whichever occurs first.
Subjects are counted once in each row, regardless of the number of events they may have had.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total.
A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

MedDRA 22.1 System Organ Class Preferred Term	Japan Placebo (N=114) n (%)	Japan Active UPA 15 mg QD (N=114) n (%)	Japan Active UPA 30 mg QD (N=115) n (%)	Overall Placebo (N=868) n (%)	Overall Active UPA 15 mg QD (N=866) n (%)	Overall Active UPA 30 mg QD (N=873) n (%)
免疫系障害	0	0	0	1 (0.1)	0	0
薬物過敏症	0	0	0	1 (0.1)	0	0
感染症および寄生虫症	1 (0.9)	1 (0.9)	0	4 (0.5)	4 (0.5)	5 (0.6)
ブドウ球菌感染性滑液包炎	0	0	0	0	0	1 (0.1)
蜂巣炎	0	0	0	1 (0.1)	0	0
心内膜炎	1 (0.9)	0	0	1 (0.1)	0	0
眼感染	0	0	0	0	1 (0.1)	0
胃腸炎	0	0	0	1 (0.1)	0	0
ヘルペス眼感染	0	0	0	0	1 (0.1)	1 (0.1)
膿痂疹	0	0	0	0	0	1 (0.1)
カポジ水痘様発疹	0	1 (0.9)	0	0	1 (0.1)	0
精巣炎	0	0	0	0	0	1 (0.1)
咽頭膿瘍	0	0	0	0	0	1 (0.1)
肺炎	0	0	0	1 (0.1)	0	0
副鼻腔炎	0	0	0	0	1 (0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or up to 30 days after the last dose of study drug in DB Period, whichever occurs first.
Subjects are counted once in each row, regardless of the number of events they may have had.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total.
A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

MedDRA 22.1 System Organ Class Preferred Term	Japan Placebo (N=114) n (%)	Japan Active UPA 15 mg QD (N=114) n (%)	Japan Active UPA 30 mg QD (N=115) n (%)	Overall Placebo (N=868) n (%)	Overall Active UPA 15 mg QD (N=866) n (%)	Overall Active UPA 30 mg QD (N=873) n (%)
感染症および寄生虫症 (Cont.)						
ブドウ球菌性敗血症	0	0	0	1 (0.1)	0	0
臨床検査	0	0	0	2 (0.2)	1 (0.1)	1 (0.1)
血中クレアチンホスホキナーゼ増加	0	0	0	1 (0.1)	1 (0.1)	0
ヘモグロビン減少	0	0	0	0	0	1 (0.1)
体重増加	0	0	0	1 (0.1)	0	0
代謝および栄養障害	0	0	0	1 (0.1)	0	1 (0.1)
食欲減退	0	0	0	0	0	1 (0.1)
低ナトリウム血症	0	0	0	1 (0.1)	0	0
筋骨格系および結合組織障害	0	0	0	1 (0.1)	1 (0.1)	0
ミオパチー	0	0	0	1 (0.1)	0	0
横紋筋融解症	0	0	0	0	1 (0.1)	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	0	0	0	0	4 (0.5)
結腸腺癌	0	0	0	0	0	1 (0.1)
肛門扁平上皮癌	0	0	0	0	0	1 (0.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or up to 30 days after the last dose of study drug in DB Period, whichever occurs first.
Subjects are counted once in each row, regardless of the number of events they may have had.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total.
A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

MedDRA 22.1 System Organ Class Preferred Term	Japan Placebo (N=114) n (%)	Japan Active UPA 15 mg QD (N=114) n (%)	Japan Active UPA 30 mg QD (N=115) n (%)	Overall Placebo (N=868) n (%)	Overall Active UPA 15 mg QD (N=866) n (%)	Overall Active UPA 30 mg QD (N=873) 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.)						
胃癌	0	0	0	0	0	1 (0.1)
浸潤性乳管癌	0	0	0	0	0	1 (0.1)
神経系障害	0	1 (0.9)	0	1 (0.1)	2 (0.2)	1 (0.1)
小脳出血	0	1 (0.9)	0	0	1 (0.1)	0
注意力障害	0	0	0	0	1 (0.1)	0
浮動性めまい	0	0	0	0	1 (0.1)	0
頭痛	0	0	0	0	1 (0.1)	1 (0.1)
片頭痛	0	0	0	1 (0.1)	0	0
精神障害	0	0	0	1 (0.1)	1 (0.1)	2 (0.2)
不安	0	0	0	1 (0.1)	1 (0.1)	0
双極性障害	0	0	0	0	0	1 (0.1)
混合性不安抑うつ障害	0	0	0	0	0	1 (0.1)
自殺企図	0	0	0	0	0	1 (0.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or up to 30 days after the last dose of study drug in DB Period, whichever occurs first.
Subjects are counted once in each row, regardless of the number of events they may have had.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total.
A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

MedDRA 22.1 System Organ Class Preferred Term	Japan Placebo (N=114) n (%)	Japan Active UPA 15 mg QD (N=114) n (%)	Japan Active UPA 30 mg QD (N=115) n (%)	Overall Placebo (N=868) n (%)	Overall Active UPA 15 mg QD (N=866) n (%)	Overall Active UPA 30 mg QD (N=873) n (%)
生殖系および乳房障害	0	0	0	1 (0.1)	0	0
生殖器病変	0	0	0	1 (0.1)	0	0
呼吸器、胸郭および縦隔障害	0	0	0	2 (0.2)	0	0
急性呼吸不全	0	0	0	1 (0.1)	0	0
肺塞栓症	0	0	0	1 (0.1)	0	0
皮膚および皮下組織障害	5 (4.4)	0	1 (0.9)	19 (2.2)	10 (1.2)	7 (0.8)
ざ瘡	0	0	0	0	1 (0.1)	1 (0.1)
アトピー性皮膚炎	4 (3.5)	0	0	14 (1.6)	7 (0.8)	3 (0.3)
全身性剥脱性皮膚炎	0	0	0	2 (0.2)	0	0
湿疹	0	0	0	2 (0.2)	0	1 (0.1)
紅斑	1 (0.9)	0	1 (0.9)	1 (0.1)	0	1 (0.1)
類乾癬	0	0	0	0	0	1 (0.1)
斑状丘疹状皮疹	0	0	0	0	1 (0.1)	0
蕁麻疹	0	0	0	0	1 (0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or up to 30 days after the last dose of study drug in DB Period, whichever occurs first.
Subjects are counted once in each row, regardless of the number of events they may have had.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total.
A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

相互参照：ISS Table 2.4　1.6.6.1

表 2.7.4.7-47. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の 100 人年あたりの治験薬の投与中止に至った有害事象（全体集団及び日本人集団）

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=135.8) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=137.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1371) (PYS=955.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1378) (PYS=974.2) Events (E/100PY)
Any adverse event	7 (5.2)	4 (2.9)	51 (5.3)	63 (6.5)
血液およびリンパ系障害	0	0	0	2 (0.2)
好中球減少症	0	0	0	2 (0.2)
胃腸障害	0	0	1 (0.1)	3 (0.3)
上腹部痛	0	0	1 (0.1)	0
鼓腸	0	0	0	1 (0.1)
胃食道逆流性疾患	0	0	0	1 (0.1)
悪心	0	0	0	1 (0.1)
一般・全身障害および投与部位の状態	0	2 (1.5)	2 (0.2)	3 (0.3)
顔面浮腫	0	1 (0.7)	0	1 (0.1)
びくびく感	0	0	0	1 (0.1)
倦怠感	0	0	1 (0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=135.8) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=137.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1371) (PYS=955.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1378) (PYS=974.2) Events (E/100PY)
一般・全身障害および投与部位の状態 (Cont.)				
末梢性浮腫	0	1 (0.7)	0	1 (0.1)
発熱	0	0	1 (0.1)	0
肝胆道系障害	0	0	1 (0.1)	0
肝機能異常	0	0	1 (0.1)	0
感染症および寄生虫症	2 (1.5)	0	11 (1.2)	20 (2.1)
気管支炎	0	0	0	1 (0.1)
ブドウ球菌感染性滑液包炎	0	0	0	1 (0.1)
蜂巣炎	0	0	1 (0.1)	0
ヘルペス性状湿疹	0	0	1 (0.1)	1 (0.1)
眼感染	0	0	1 (0.1)	0
B型肝炎	0	0	0	1 (0.1)
ヘルペス眼感染	0	0	1 (0.1)	1 (0.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=135.8) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=137.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1371) (PYS=955.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1378) (PYS=974.2) Events (E/100PY)
感染症および寄生虫症 (Cont.)				
単純ヘルペス	0	0	0	3 (0.3)
帯状疱疹	0	0	0	1 (0.1)
膿痂疹	0	0	1 (0.1)	0
カポジ水痘様発疹	1 (0.7)	0	1 (0.1)	1 (0.1)
精巣炎	0	0	0	1 (0.1)
骨髄炎	0	0	0	1 (0.1)
咽頭膿瘍	0	0	0	1 (0.1)
咽頭扁桃炎	0	0	1 (0.1)	0
ニューモシスチス・イロベチイ肺炎	1 (0.7)	0	1 (0.1)	0
肺炎	0	0	1 (0.1)	1 (0.1)
術後創感染	0	0	0	1 (0.1)
膿皮症	0	0	0	1 (0.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=135.8) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=137.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1371) (PYS=955.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1378) (PYS=974.2) Events (E/100PY)
感染症および寄生虫症 (Cont.)				
ライノウイルス感染	0	0	0	1 (0.1)
敗血症	0	0	0	1 (0.1)
副鼻腔炎	0	0	1 (0.1)	0
ブドウ球菌性敗血症	0	0	0	1 (0.1)
結核	0	0	0	1 (0.1)
尿路感染	0	0	1 (0.1)	0
臨床検査	0	0	3 (0.3)	11 (1.1)
アラニンアミノトランスフェラーゼ増加	0	0	0	2 (0.2)
アスパラギン酸アミノトランスフェラーゼ増加	0	0	0	2 (0.2)
血中クレアチンホスホキナーゼ増加	0	0	1 (0.1)	1 (0.1)
血液培養陽性	0	0	0	1 (0.1)
心雑音	0	0	0	1 (0.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=135.8) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=137.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1371) (PYS=955.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1378) (PYS=974.2) Events (E/100PY)
臨床検査 (Cont.)				
尿培養陽性	0	0	0	1 (0.1)
ヘモグロビン減少	0	0	0	2 (0.2)
尿妊娠反応陽性	0	0	1 (0.1)	0
体重増加	0	0	1 (0.1)	1 (0.1)
代謝および栄養障害	0	0	0	1 (0.1)
食欲減退	0	0	0	1 (0.1)
筋骨格系および結合組織障害	0	0	1 (0.1)	2 (0.2)
背部痛	0	0	0	1 (0.1)
筋肉痛	0	0	0	1 (0.1)
横紋筋融解症	0	0	1 (0.1)	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	0	0	5 (0.5)
結腸腺癌	0	0	0	1 (0.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=135.8) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=137.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1371) (PYS=955.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1378) (PYS=974.2) 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.)				
肛門扁平上皮癌	0	0	0	1 (0.1)
皮膚T細胞性リンパ腫	0	0	0	1 (0.1)
胃癌	0	0	0	1 (0.1)
浸潤性乳管癌	0	0	0	1 (0.1)
神経系障害	1 (0.7)	0	6 (0.6)	2 (0.2)
小脳出血	1 (0.7)	0	1 (0.1)	0
脳血管発作	0	0	0	1 (0.1)
注意力障害	0	0	1 (0.1)	0
浮動性めまい	0	0	1 (0.1)	0
頭痛	0	0	1 (0.1)	1 (0.1)
虚血性脳卒中	0	0	1 (0.1)	0
くも膜下出血	0	0	1 (0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=135.8) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=137.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1371) (PYS=955.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1378) (PYS=974.2) Events (E/100PY)
精神障害	1 (0.7)	0	3 (0.3)	3 (0.3)
不安	0	0	1 (0.1)	0
双極性障害	0	0	0	1 (0.1)
うつ病	0	0	1 (0.1)	0
混合性不安抑うつ障害	0	0	0	1 (0.1)
睡眠障害	1 (0.7)	0	1 (0.1)	0
自殺企図	0	0	0	1 (0.1)
呼吸器、胸郭および縦隔障害	0	0	4 (0.4)	0
喘息	0	0	2 (0.2)	0
咳嗽	0	0	1 (0.1)	0
呼吸困難	0	0	1 (0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=135.8) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=137.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1371) (PYS=955.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1378) (PYS=974.2) Events (E/100PY)
皮膚および皮下組織障害	3 (2.2)	2 (1.5)	19 (2.0)	11 (1.1)
ざ瘡	0	0	1 (0.1)	1 (0.1)
アレルギー性皮膚炎	0	0	0	1 (0.1)
アトピー性皮膚炎	2 (1.5)	1 (0.7)	14 (1.5)	4 (0.4)
湿疹	0	0	0	2 (0.2)
紅斑	0	1 (0.7)	0	1 (0.1)
類乾癬	0	0	0	1 (0.1)
そう痒症	1 (0.7)	0	2 (0.2)	0
丘疹性皮疹	0	0	0	1 (0.1)
中毒性表皮壊死融解症	0	0	1 (0.1)	0
蕁麻疹	0	0	1 (0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：ISS Table 2.4　2.3.6

表 2.7.4.7-48. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の青少年被験者及び成人被験者の 100 人年あたりの治験薬の投与中止に至った有害事象（全体集団及び日本人集団）

Subgroup: Adolescent

	Japan		Overall	
MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=16) (PYS=11.7) Events (E/100PY)	UPA 30 mg QD (N=16) (PYS=11.3) Events (E/100PY)	UPA 15 mg QD (N=181) (PYS=132.5) Events (E/100PY)	UPA 30 mg QD (N=180) (PYS=134.1) Events (E/100PY)
Any adverse event	1 (8.6)	0	8 (6.0)	9 (6.7)
一般・全身障害および投与部位の状態	0	0	1 (0.8)	0
発熱	0	0	1 (0.8)	0
肝胆道系障害	0	0	1 (0.8)	0
肝機能異常	0	0	1 (0.8)	0
感染症および寄生虫症	0	0	1 (0.8)	5 (3.7)
骨髄炎	0	0	0	1 (0.7)
咽頭扁桃炎	0	0	1 (0.8)	0
肺炎	0	0	0	1 (0.7)
膿皮症	0	0	0	1 (0.7)
敗血症	0	0	0	1 (0.7)
ブドウ球菌性敗血症	0	0	0	1 (0.7)
臨床検査	0	0	0	3 (2.2)
血液培養陽性	0	0	0	1 (0.7)
心雑音	0	0	0	1 (0.7)
尿培養陽性	0	0	0	1 (0.7)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=16) (PYS=11.7) Events (E/100PY)	Japan UPA 30 mg QD (N=16) (PYS=11.3) Events (E/100PY)	Overall UPA 15 mg QD (N=181) (PYS=132.5) Events (E/100PY)	Overall UPA 30 mg QD (N=180) (PYS=134.1) Events (E/100PY)
精神障害	0	0	1 (0.8)	0
うつ病	0	0	1 (0.8)	0
呼吸器、胸郭および縦隔障害	0	0	1 (0.8)	0
喘息	0	0	1 (0.8)	0
皮膚および皮下組織障害	1 (8.6)	0	3 (2.3)	1 (0.7)
アトピー性皮膚炎	1 (8.6)	0	2 (1.5)	1 (0.7)
そう痒症	0	0	1 (0.8)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

Subgroup: Adult

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=161) (PYS=124.1) Events (E/100PY)	Japan UPA 30 mg QD (N=165) (PYS=126.0) Events (E/100PY)	Overall UPA 15 mg QD (N=1190) (PYS=822.4) Events (E/100PY)	Overall UPA 30 mg QD (N=1198) (PYS=840.1) Events (E/100PY)
Any adverse event	6 (4.8)	4 (3.2)	43 (5.2)	54 (6.4)
血液およびリンパ系障害	0	0	0	2 (0.2)
好中球減少症	0	0	0	2 (0.2)
胃腸障害	0	0	1 (0.1)	3 (0.4)
上腹部痛	0	0	1 (0.1)	0
鼓腸	0	0	0	1 (0.1)
胃食道逆流性疾患	0	0	0	1 (0.1)
悪心	0	0	0	1 (0.1)
一般・全身障害および投与部位の状態	0	2 (1.6)	1 (0.1)	3 (0.4)
顔面浮腫	0	1 (0.8)	0	1 (0.1)
びくびく感	0	0	0	1 (0.1)
倦怠感	0	0	1 (0.1)	0
末梢性浮腫	0	1 (0.8)	0	1 (0.1)
感染症および寄生虫症	2 (1.6)	0	10 (1.2)	15 (1.8)
気管支炎	0	0	0	1 (0.1)
ブドウ球菌感染性滑液包炎	0	0	0	1 (0.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=161) (PYS=124.1) Events (E/100PY)	Japan UPA 30 mg QD (N=165) (PYS=126.0) Events (E/100PY)	Overall UPA 15 mg QD (N=1190) (PYS=822.4) Events (E/100PY)	Overall UPA 30 mg QD (N=1198) (PYS=840.1) Events (E/100PY)
感染症および寄生虫症 (Cont.)				
蜂巣炎	0	0	1 (0.1)	0
ヘルペス性状湿疹	0	0	1 (0.1)	1 (0.1)
眼感染	0	0	1 (0.1)	0
B型肝炎	0	0	0	1 (0.1)
ヘルペス眼感染	0	0	1 (0.1)	1 (0.1)
単純ヘルペス	0	0	0	3 (0.4)
帯状疱疹	0	0	0	1 (0.1)
膿痂疹	0	0	1 (0.1)	0
カポジ水痘様発疹	1 (0.8)	0	1 (0.1)	1 (0.1)
精巣炎	0	0	0	1 (0.1)
咽頭膿瘍	0	0	0	1 (0.1)
ニューモシスチス・イロベチイ肺炎	1 (0.8)	0	1 (0.1)	0
肺炎	0	0	1 (0.1)	0
術後創感染	0	0	0	1 (0.1)
ライノウイルス感染	0	0	0	1 (0.1)
副鼻腔炎	0	0	1 (0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=161) (PYS=124.1) Events (E/100PY)	Japan UPA 30 mg QD (N=165) (PYS=126.0) Events (E/100PY)	Overall UPA 15 mg QD (N=1190) (PYS=822.4) Events (E/100PY)	Overall UPA 30 mg QD (N=1198) (PYS=840.1) Events (E/100PY)
感染症および寄生虫症 (Cont.)				
結核	0	0	0	1 (0.1)
尿路感染	0	0	1 (0.1)	0
臨床検査	0	0	3 (0.4)	8 (1.0)
アラニンアミノトランスフェラーゼ増加	0	0	0	2 (0.2)
アスパラギン酸アミノトランスフェラーゼ増加	0	0	0	2 (0.2)
血中クレアチンホスホキナーゼ増加	0	0	1 (0.1)	1 (0.1)
ヘモグロビン減少	0	0	0	2 (0.2)
尿妊娠反応陽性	0	0	1 (0.1)	0
体重増加	0	0	1 (0.1)	1 (0.1)
代謝および栄養障害	0	0	0	1 (0.1)
食欲減退	0	0	0	1 (0.1)
筋骨格系および結合組織障害	0	0	1 (0.1)	2 (0.2)
背部痛	0	0	0	1 (0.1)
筋肉痛	0	0	0	1 (0.1)
横紋筋融解症	0	0	1 (0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=161) (PYS=124.1) Events (E/100PY)	Japan UPA 30 mg QD (N=165) (PYS=126.0) Events (E/100PY)	Overall UPA 15 mg QD (N=1190) (PYS=822.4) Events (E/100PY)	Overall UPA 30 mg QD (N=1198) (PYS=840.1) 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）	0	0	0	5 (0.6)
結腸腺癌	0	0	0	1 (0.1)
肛門扁平上皮癌	0	0	0	1 (0.1)
皮膚T細胞性リンパ腫	0	0	0	1 (0.1)
胃癌	0	0	0	1 (0.1)
浸潤性乳管癌	0	0	0	1 (0.1)
神経系障害	1 (0.8)	0	6 (0.7)	2 (0.2)
小脳出血	1 (0.8)	0	1 (0.1)	0
脳血管発作	0	0	0	1 (0.1)
注意力障害	0	0	1 (0.1)	0
浮動性めまい	0	0	1 (0.1)	0
頭痛	0	0	1 (0.1)	1 (0.1)
虚血性脳卒中	0	0	1 (0.1)	0
くも膜下出血	0	0	1 (0.1)	0
精神障害	1 (0.8)	0	2 (0.2)	3 (0.4)
不安	0	0	1 (0.1)	0
双極性障害	0	0	0	1 (0.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=161) (PYS=124.1) Events (E/100PY)	Japan UPA 30 mg QD (N=165) (PYS=126.0) Events (E/100PY)	Overall UPA 15 mg QD (N=1190) (PYS=822.4) Events (E/100PY)	Overall UPA 30 mg QD (N=1198) (PYS=840.1) Events (E/100PY)
精神障害 (Cont.)				
混合性不安抑うつ障害	0	0	0	1 (0.1)
睡眠障害	1 (0.8)	0	1 (0.1)	0
自殺企図	0	0	0	1 (0.1)
呼吸器、胸郭および縦隔障害	0	0	3 (0.4)	0
喘息	0	0	1 (0.1)	0
咳嗽	0	0	1 (0.1)	0
呼吸困難	0	0	1 (0.1)	0
皮膚および皮下組織障害	2 (1.6)	2 (1.6)	16 (1.9)	10 (1.2)
ざ瘡	0	0	1 (0.1)	1 (0.1)
アレルギー性皮膚炎	0	0	0	1 (0.1)
アトピー性皮膚炎	1 (0.8)	1 (0.8)	12 (1.5)	3 (0.4)
湿疹	0	0	0	2 (0.2)
紅斑	0	1 (0.8)	0	1 (0.1)
類乾癬	0	0	0	1 (0.1)
そう痒症	1 (0.8)	0	1 (0.1)	0
丘疹性皮疹	0	0	0	1 (0.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=161) (PYS=124.1) Events (E/100PY)	Japan UPA 30 mg QD (N=165) (PYS=126.0) Events (E/100PY)	Overall UPA 15 mg QD (N=1190) (PYS=822.4) Events (E/100PY)	Overall UPA 30 mg QD (N=1198) (PYS=840.1) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)				
中毒性表皮壊死融解症	0	0	1 (0.1)	0
蕁麻疹	0	0	1 (0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：ISS Table 2.4　2.9.4.1

表 2.7.4.7-49. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の 100 人年あたりの治験薬の投与中止に至った有害事象（全体集団及び日本人集団，更新時）

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=225.5) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=228.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1372) (PYS=1407.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1380) (PYS=1446.5) Events (E/100PY)
Any adverse event	8 (3.5)	7 (3.1)	65 (4.6)	79 (5.5)
血液およびリンパ系障害	0	0	0	3 (0.2)
好中球減少症	0	0	0	3 (0.2)
心臓障害	0	0	0	1 (<0.1)
心筋梗塞	0	0	0	1 (<0.1)
先天性、家族性および遺伝性障害	0	0	1 (<0.1)	0
ネザートン症候群	0	0	1 (<0.1)	0
胃腸障害	0	0	1 (<0.1)	3 (0.2)
上腹部痛	0	0	1 (<0.1)	0
鼓腸	0	0	0	1 (<0.1)
胃食道逆流性疾患	0	0	0	1 (<0.1)
悪心	0	0	0	1 (<0.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=225.5) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=228.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1372) (PYS=1407.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1380) (PYS=1446.5) Events (E/100PY)
一般・全身障害および投与部位の状態	0	2 (0.9)	2 (0.1)	3 (0.2)
顔面浮腫	0	1 (0.4)	0	1 (<0.1)
びくびく感	0	0	0	1 (<0.1)
倦怠感	0	0	1 (<0.1)	0
末梢性浮腫	0	1 (0.4)	0	1 (<0.1)
発熱	0	0	1 (<0.1)	0
肝胆道系障害	0	1 (0.4)	1 (<0.1)	1 (<0.1)
肝機能異常	0	1 (0.4)	1 (<0.1)	1 (<0.1)
感染症および寄生虫症	2 (0.9)	0	15 (1.1)	23 (1.6)
気管支炎	0	0	0	1 (<0.1)
ブドウ球菌感染性滑液包炎	0	0	0	1 (<0.1)
蜂巣炎	0	0	1 (<0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=225.5) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=228.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1372) (PYS=1407.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1380) (PYS=1446.5) Events (E/100PY)
感染症および寄生虫症 (Cont.)				
ヘルペス性状湿疹	0	0	1 (<0.1)	2 (0.1)
眼感染	0	0	1 (<0.1)	0
毛包炎	0	0	1 (<0.1)	0
Ｂ型肝炎	0	0	0	1 (<0.1)
ヘルペス眼感染	0	0	1 (<0.1)	1 (<0.1)
単純ヘルペス	0	0	0	3 (0.2)
帯状疱疹	0	0	1 (<0.1)	1 (<0.1)
播種性帯状疱疹	0	0	0	1 (<0.1)
膿痂疹	0	0	2 (0.1)	0
カポジ水痘様発疹	1 (0.4)	0	1 (<0.1)	1 (<0.1)
精巣炎	0	0	0	1 (<0.1)
骨髄炎	0	0	0	1 (<0.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=225.5) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=228.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1372) (PYS=1407.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1380) (PYS=1446.5) Events (E/100PY)
感染症および寄生虫症 (Cont.)				
咽頭膿瘍	0	0	0	1 (<0.1)
咽頭扁桃炎	0	0	1 (<0.1)	0
ニューモシスチス・イロベチイ肺炎	1 (0.4)	0	1 (<0.1)	0
肺炎	0	0	1 (<0.1)	1 (<0.1)
術後創感染	0	0	0	1 (<0.1)
肺結核	0	0	1 (<0.1)	0
腎盂腎炎	0	0	0	1 (<0.1)
膿皮症	0	0	0	1 (<0.1)
ライノウイルス感染	0	0	0	1 (<0.1)
敗血症	0	0	0	1 (<0.1)
副鼻腔炎	0	0	1 (<0.1)	0
ブドウ球菌性敗血症	0	0	0	1 (<0.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=225.5) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=228.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1372) (PYS=1407.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1380) (PYS=1446.5) Events (E/100PY)
感染症および寄生虫症 (Cont.)				
結核	0	0	0	1 (<0.1)
尿路感染	0	0	1 (<0.1)	0
臨床検査	0	2 (0.9)	6 (0.4)	15 (1.0)
アラニンアミノトランスフェラーゼ増加	0	1 (0.4)	0	4 (0.3)
アスパラギン酸アミノトランスフェラーゼ増加	0	0	0	3 (0.2)
血中クレアチンホスホキナーゼ増加	0	0	1 (<0.1)	2 (0.1)
心雑音	0	0	0	1 (<0.1)
心電図ＱＴ間隔異常	0	0	2 (0.1)	0
ヘモグロビン減少	0	0	0	2 (0.1)
リンパ球形態異常	0	1 (0.4)	0	1 (<0.1)
尿妊娠反応陽性	0	0	1 (<0.1)	0
トランスアミナーゼ上昇	0	0	0	1 (<0.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=225.5) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=228.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1372) (PYS=1407.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1380) (PYS=1446.5) Events (E/100PY)
臨床検査 (Cont.)				
体重増加	0	0	2 (0.1)	1 (<0.1)
代謝および栄養障害	0	0	0	2 (0.1)
食欲減退	0	0	0	1 (<0.1)
食欲亢進	0	0	0	1 (<0.1)
筋骨格系および結合組織障害	0	0	1 (<0.1)	2 (0.1)
背部痛	0	0	0	1 (<0.1)
筋肉痛	0	0	0	1 (<0.1)
横紋筋融解症	0	0	1 (<0.1)	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	1 (0.4)	0	2 (0.1)	5 (0.3)
結腸腺癌	0	0	0	1 (<0.1)
肛門扁平上皮癌	0	0	0	1 (<0.1)
乳癌	1 (0.4)	0	1 (<0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=225.5) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=228.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1372) (PYS=1407.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1380) (PYS=1446.5) 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.)				
皮膚T細胞性リンパ腫	0	0	0	1 (<0.1)
胃癌	0	0	0	1 (<0.1)
浸潤性乳管癌	0	0	0	1 (<0.1)
口腔内扁平上皮癌	0	0	1 (<0.1)	0
神経系障害	1 (0.4)	0	6 (0.4)	3 (0.2)
小脳出血	1 (0.4)	0	1 (<0.1)	0
脳血管発作	0	0	0	1 (<0.1)
注意力障害	0	0	1 (<0.1)	0
浮動性めまい	0	0	1 (<0.1)	0
頭痛	0	0	1 (<0.1)	1 (<0.1)
虚血性脳卒中	0	0	1 (<0.1)	0
多発性硬化症	0	0	0	1 (<0.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=225.5) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=228.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1372) (PYS=1407.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1380) (PYS=1446.5) Events (E/100PY)
神経系障害 (Cont.)				
くも膜下出血	0	0	1 (<0.1)	0
精神障害	1 (0.4)	0	3 (0.2)	3 (0.2)
不安	0	0	1 (<0.1)	0
双極性障害	0	0	0	1 (<0.1)
うつ病	0	0	1 (<0.1)	0
混合性不安抑うつ障害	0	0	0	1 (<0.1)
睡眠障害	1 (0.4)	0	1 (<0.1)	0
自殺企図	0	0	0	1 (<0.1)
呼吸器、胸郭および縦隔障害	0	0	5 (0.4)	0
喘息	0	0	2 (0.1)	0
咳嗽	0	0	1 (<0.1)	0
呼吸困難	0	0	1 (<0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=225.5) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=228.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1372) (PYS=1407.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1380) (PYS=1446.5) Events (E/100PY)
呼吸器、胸郭および縦隔障害 (Cont.)				
肺塞栓症	0	0	1 (<0.1)	0
皮膚および皮下組織障害	3 (1.3)	2 (0.9)	21 (1.5)	15 (1.0)
ざ瘡	0	0	1 (<0.1)	3 (0.2)
アレルギー性皮膚炎	0	0	0	1 (<0.1)
アトピー性皮膚炎	2 (0.9)	1 (0.4)	16 (1.1)	5 (0.3)
湿疹	0	0	0	2 (0.1)
紅斑	0	1 (0.4)	0	1 (<0.1)
類乾癬	0	0	0	1 (<0.1)
光線過敏性反応	0	0	0	1 (<0.1)
そう痒症	1 (0.4)	0	2 (0.1)	0
丘疹性皮疹	0	0	0	1 (<0.1)
中毒性表皮壊死融解症	0	0	1 (<0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=225.5) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=228.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1372) (PYS=1407.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1380) (PYS=1446.5) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)				
蕁麻疹	0	0	1 (<0.1)	0
血管障害	0	0	1 (<0.1)	0
深部静脈血栓症	0	0	1 (<0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：Updated ISS Table 2.4　2.3.6

表 2.7.4.7-50. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の青少年被験者及び成人被験者の 100 人年あたりの治験薬の投与中止に至った有害事象（全体集団及び日本人集団，更新時）

	Japan		Overall	
MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=16) (PYS=19.9) Events (E/100PY)	UPA 30 mg QD (N=16) (PYS=18.3) Events (E/100PY)	UPA 15 mg QD (N=181) (PYS=194.3) Events (E/100PY)	UPA 30 mg QD (N=180) (PYS=197.0) Events (E/100PY)
Subgroup: Adolescent				
Any adverse event	1 (5.0)	1 (5.5)	10 (5.1)	9 (4.6)
一般・全身障害および投与部位の状態	0	0	1 (0.5)	0
発熱	0	0	1 (0.5)	0
肝胆道系障害	0	0	1 (0.5)	0
肝機能異常	0	0	1 (0.5)	0
感染症および寄生虫症	0	0	1 (0.5)	5 (2.5)
骨髄炎	0	0	0	1 (0.5)
咽頭扁桃炎	0	0	1 (0.5)	0
肺炎	0	0	0	1 (0.5)
膿皮症	0	0	0	1 (0.5)
敗血症	0	0	0	1 (0.5)
ブドウ球菌性敗血症	0	0	0	1 (0.5)
臨床検査	0	1 (5.5)	1 (0.5)	2 (1.0)
心雑音	0	0	0	1 (0.5)
心電図ＱＴ間隔異常	0	0	1 (0.5)	0
リンパ球形態異常	0	1 (5.5)	0	1 (0.5)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=16) (PYS=19.9) Events (E/100PY)	Japan UPA 30 mg QD (N=16) (PYS=18.3) Events (E/100PY)	Overall UPA 15 mg QD (N=181) (PYS=194.3) Events (E/100PY)	Overall UPA 30 mg QD (N=180) (PYS=197.0) Events (E/100PY)
Subgroup: Adolescent				
精神障害	0	0	1 (0.5)	0
うつ病	0	0	1 (0.5)	0
呼吸器、胸郭および縦隔障害	0	0	1 (0.5)	0
喘息	0	0	1 (0.5)	0
皮膚および皮下組織障害	1 (5.0)	0	4 (2.1)	2 (1.0)
ざ瘡	0	0	0	1 (0.5)
アトピー性皮膚炎	1 (5.0)	0	3 (1.5)	1 (0.5)
そう痒症	0	0	1 (0.5)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=161) (PYS=205.6) Events (E/100PY)	Japan UPA 30 mg QD (N=165) (PYS=210.0) Events (E/100PY)	Overall UPA 15 mg QD (N=1191) (PYS=1212.7) Events (E/100PY)	Overall UPA 30 mg QD (N=1200) (PYS=1249.5) Events (E/100PY)
Subgroup: Adult				
Any adverse event	7 (3.4)	6 (2.9)	55 (4.5)	70 (5.6)
血液およびリンパ系障害	0	0	0	3 (0.2)
好中球減少症	0	0	0	3 (0.2)
心臓障害	0	0	0	1 (<0.1)
心筋梗塞	0	0	0	1 (<0.1)
先天性、家族性および遺伝性障害	0	0	1 (<0.1)	0
ネザートン症候群	0	0	1 (<0.1)	0
胃腸障害	0	0	1 (<0.1)	3 (0.2)
上腹部痛	0	0	1 (<0.1)	0
鼓腸	0	0	0	1 (<0.1)
胃食道逆流性疾患	0	0	0	1 (<0.1)
悪心	0	0	0	1 (<0.1)
一般・全身障害および投与部位の状態	0	2 (1.0)	1 (<0.1)	3 (0.2)
顔面浮腫	0	1 (0.5)	0	1 (<0.1)
びくびく感	0	0	0	1 (<0.1)
倦怠感	0	0	1 (<0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=161) (PYS=205.6) Events (E/100PY)	Japan UPA 30 mg QD (N=165) (PYS=210.0) Events (E/100PY)	Overall UPA 15 mg QD (N=1191) (PYS=1212.7) Events (E/100PY)	Overall UPA 30 mg QD (N=1200) (PYS=1249.5) Events (E/100PY)
Subgroup: Adult				
一般・全身障害および投与部位の状態 (Cont.)				
末梢性浮腫	0	1 (0.5)	0	1 (<0.1)
肝胆道系障害	0	1 (0.5)	0	1 (<0.1)
肝機能異常	0	1 (0.5)	0	1 (<0.1)
感染症および寄生虫症	2 (1.0)	0	14 (1.2)	18 (1.4)
気管支炎	0	0	0	1 (<0.1)
ブドウ球菌感染性滑液包炎	0	0	0	1 (<0.1)
蜂巣炎	0	0	1 (<0.1)	0
ヘルペス性状湿疹	0	0	1 (<0.1)	2 (0.2)
眼感染	0	0	1 (<0.1)	0
毛包炎	0	0	1 (<0.1)	0
Ｂ型肝炎	0	0	0	1 (<0.1)
ヘルペス眼感染	0	0	1 (<0.1)	1 (<0.1)
単純ヘルペス	0	0	0	3 (0.2)
帯状疱疹	0	0	1 (<0.1)	1 (<0.1)
播種性帯状疱疹	0	0	0	1 (<0.1)
膿痂疹	0	0	2 (0.2)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=161) (PYS=205.6) Events (E/100PY)	Japan UPA 30 mg QD (N=165) (PYS=210.0) Events (E/100PY)	Overall UPA 15 mg QD (N=1191) (PYS=1212.7) Events (E/100PY)	Overall UPA 30 mg QD (N=1200) (PYS=1249.5) Events (E/100PY)
Subgroup: Adult				
感染症および寄生虫症 (Cont.)				
カポジ水痘様発疹	1 (0.5)	0	1 (<0.1)	1 (<0.1)
精巣炎	0	0	0	1 (<0.1)
咽頭膿瘍	0	0	0	1 (<0.1)
ニューモシスチス・イロベチイ肺炎	1 (0.5)	0	1 (<0.1)	0
肺炎	0	0	1 (<0.1)	0
術後創感染	0	0	0	1 (<0.1)
肺結核	0	0	1 (<0.1)	0
腎盂腎炎	0	0	0	1 (<0.1)
ライノウイルス感染	0	0	0	1 (<0.1)
副鼻腔炎	0	0	1 (<0.1)	0
結核	0	0	0	1 (<0.1)
尿路感染	0	0	1 (<0.1)	0
臨床検査	0	1 (0.5)	5 (0.4)	13 (1.0)
アラニンアミノトランスフェラーゼ増加	0	1 (0.5)	0	4 (0.3)
アスパラギン酸アミノトランスフェラーゼ増加	0	0	0	3 (0.2)
血中クレアチンホスホキナーゼ増加	0	0	1 (<0.1)	2 (0.2)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=161) (PYS=205.6) Events (E/100PY)	Japan UPA 30 mg QD (N=165) (PYS=210.0) Events (E/100PY)	Overall UPA 15 mg QD (N=1191) (PYS=1212.7) Events (E/100PY)	Overall UPA 30 mg QD (N=1200) (PYS=1249.5) Events (E/100PY)
Subgroup: Adult				
臨床検査 (Cont.)				
心電図ＱＴ間隔異常	0	0	1 (<0.1)	0
ヘモグロビン減少	0	0	0	2 (0.2)
尿妊娠反応陽性	0	0	1 (<0.1)	0
トランスアミナーゼ上昇	0	0	0	1 (<0.1)
体重増加	0	0	2 (0.2)	1 (<0.1)
代謝および栄養障害	0	0	0	2 (0.2)
食欲減退	0	0	0	1 (<0.1)
食欲亢進	0	0	0	1 (<0.1)
筋骨格系および結合組織障害	0	0	1 (<0.1)	2 (0.2)
背部痛	0	0	0	1 (<0.1)
筋肉痛	0	0	0	1 (<0.1)
横紋筋融解症	0	0	1 (<0.1)	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	1 (0.5)	0	2 (0.2)	5 (0.4)
結腸腺癌	0	0	0	1 (<0.1)
肛門扁平上皮癌	0	0	0	1 (<0.1)
乳癌	1 (0.5)	0	1 (<0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=161) (PYS=205.6) Events (E/100PY)	Japan UPA 30 mg QD (N=165) (PYS=210.0) Events (E/100PY)	Overall UPA 15 mg QD (N=1191) (PYS=1212.7) Events (E/100PY)	Overall UPA 30 mg QD (N=1200) (PYS=1249.5) Events (E/100PY)
Subgroup: Adult				
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.)				
皮膚T細胞性リンパ腫	0	0	0	1 (<0.1)
胃癌	0	0	0	1 (<0.1)
浸潤性乳管癌	0	0	0	1 (<0.1)
口腔内扁平上皮癌	0	0	1 (<0.1)	0
神経系障害	1 (0.5)	0	6 (0.5)	3 (0.2)
小脳出血	1 (0.5)	0	1 (<0.1)	0
脳血管発作	0	0	0	1 (<0.1)
注意力障害	0	0	1 (<0.1)	0
浮動性めまい	0	0	1 (<0.1)	0
頭痛	0	0	1 (<0.1)	1 (<0.1)
虚血性脳卒中	0	0	1 (<0.1)	0
多発性硬化症	0	0	0	1 (<0.1)
くも膜下出血	0	0	1 (<0.1)	0
精神障害	1 (0.5)	0	2 (0.2)	3 (0.2)
不安	0	0	1 (<0.1)	0
双極性障害	0	0	0	1 (<0.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=161) (PYS=205.6) Events (E/100PY)	Japan UPA 30 mg QD (N=165) (PYS=210.0) Events (E/100PY)	Overall UPA 15 mg QD (N=1191) (PYS=1212.7) Events (E/100PY)	Overall UPA 30 mg QD (N=1200) (PYS=1249.5) Events (E/100PY)
Subgroup: Adult				
精神障害 (Cont.)				
混合性不安抑うつ障害	0	0	0	1 (<0.1)
睡眠障害	1 (0.5)	0	1 (<0.1)	0
自殺企図	0	0	0	1 (<0.1)
呼吸器、胸郭および縦隔障害	0	0	4 (0.3)	0
喘息	0	0	1 (<0.1)	0
咳嗽	0	0	1 (<0.1)	0
呼吸困難	0	0	1 (<0.1)	0
肺塞栓症	0	0	1 (<0.1)	0
皮膚および皮下組織障害	2 (1.0)	2 (1.0)	17 (1.4)	13 (1.0)
ざ瘡	0	0	1 (<0.1)	2 (0.2)
アレルギー性皮膚炎	0	0	0	1 (<0.1)
アトピー性皮膚炎	1 (0.5)	1 (0.5)	13 (1.1)	4 (0.3)
湿疹	0	0	0	2 (0.2)
紅斑	0	1 (0.5)	0	1 (<0.1)
類乾癬	0	0	0	1 (<0.1)
光線過敏性反応	0	0	0	1 (<0.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=161) (PYS=205.6) Events (E/100PY)	Japan UPA 30 mg QD (N=165) (PYS=210.0) Events (E/100PY)	Overall UPA 15 mg QD (N=1191) (PYS=1212.7) Events (E/100PY)	Overall UPA 30 mg QD (N=1200) (PYS=1249.5) Events (E/100PY)
Subgroup: Adult				
皮膚および皮下組織障害 (Cont.)				
そう痒症	1 (0.5)	0	1 (<0.1)	0
丘疹性皮疹	0	0	0	1 (<0.1)
中毒性表皮壊死融解症	0	0	1 (<0.1)	0
蕁麻疹	0	0	1 (<0.1)	0
血管障害	0	0	1 (<0.1)	0
深部静脈血栓症	0	0	1 (<0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：Updated ISS Table 2.4　2.9.4.1

表 2.7.4.7-51. 投与 16 週時までの治験薬の投与中止に至った有害事象（Safety_DB_M 集団）：M16-045 試験

MedDRA 22.1 System Organ Class Preferred Term	Placebo (N=281) n (%)	Active UPA 15 mg QD (N=281) n (%)	Active UPA 30 mg QD (N=285) n (%)	Total (N=566) n (%)
Any adverse event	12 (4.3)	4 (1.4)	11 (3.9)	15 (2.7)
血液およびリンパ系障害	0	0	1 (0.4)	1 (0.2)
好中球減少症	0	0	1 (0.4)	1 (0.2)
胃腸障害	0	0	1 (0.4)	1 (0.2)
鼓腸	0	0	1 (0.4)	1 (0.2)
一般・全身障害および投与部位の状態	0	0	2 (0.7)	2 (0.4)
顔面浮腫	0	0	1 (0.4)	1 (0.2)
びくびく感	0	0	1 (0.4)	1 (0.2)
免疫系障害	2 (0.7)	0	0	0
薬物過敏症	2 (0.7)	0	0	0
感染症および寄生虫症	1 (0.4)	1 (0.4)	1 (0.4)	2 (0.4)
眼感染	0	1 (0.4)	0	1 (0.2)
胃腸炎	1 (0.4)	0	0	0
咽頭膿瘍	0	0	1 (0.4)	1 (0.2)
臨床検査	0	0	1 (0.4)	1 (0.2)
ヘモグロビン減少	0	0	1 (0.4)	1 (0.2)

Note: Treatment-emergent adverse events in DB Period are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or no more than 30 days after the last dose of study drug in DB Period, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.

MedDRA 22.1 System Organ Class Preferred Term	Placebo (N=281) n (%)	Active UPA 15 mg QD (N=281) n (%)	Active UPA 30 mg QD (N=285) n (%)	Total (N=566) n (%)
代謝および栄養障害	0	0	1 (0.4)	1 (0.2)
食欲減退	0	0	1 (0.4)	1 (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）	0	0	2 (0.7)	2 (0.4)
胃癌	0	0	1 (0.4)	1 (0.2)
浸潤性乳管癌	0	0	1 (0.4)	1 (0.2)
神経系障害	1 (0.4)	1 (0.4)	1 (0.4)	2 (0.4)
注意力障害	0	1 (0.4)	0	1 (0.2)
浮動性めまい	0	1 (0.4)	0	1 (0.2)
頭痛	0	1 (0.4)	1 (0.4)	2 (0.4)
片頭痛	1 (0.4)	0	0	0
精神障害	1 (0.4)	0	0	0
不安	1 (0.4)	0	0	0
皮膚および皮下組織障害	7 (2.5)	2 (0.7)	4 (1.4)	6 (1.1)
ざ瘡	0	1 (0.4)	1 (0.4)	2 (0.4)
アトピー性皮膚炎	5 (1.8)	1 (0.4)	1 (0.4)	2 (0.4)
全身性剥脱性皮膚炎	1 (0.4)	0	0	0
紅斑	1 (0.4)	0	1 (0.4)	1 (0.2)
類乾癬	0	0	1 (0.4)	1 (0.2)

Note: Treatment-emergent adverse events in DB Period are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or no more than 30 days after the last dose of study drug in DB Period, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.

相互参照：M16-045 試験 CSR W16 Table 14.3　2.3.1

表 2.7.4.7-52. 投与 52 週時データカットオフまでの治験薬の投与中止に至った有害事象（ALL_UPA_M 集団）：M16-045 試験

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=401) n (%)	UPA 30 mg QD (N=408) n (%)	Total (N=809) n (%)
Any adverse event	18 (4.5)	29 (7.1)	47 (5.8)
血液およびリンパ系障害	0	2 (0.5)	2 (0.2)
好中球減少症	0	2 (0.5)	2 (0.2)
心臓障害	0	1 (0.2)	1 (0.1)
心筋梗塞	0	1 (0.2)	1 (0.1)
先天性、家族性および遺伝性障害	1 (0.2)	0	1 (0.1)
ネザートン症候群	1 (0.2)	0	1 (0.1)
胃腸障害	0	1 (0.2)	1 (0.1)
鼓腸	0	1 (0.2)	1 (0.1)
一般・全身障害および投与部位の状態	1 (0.2)	2 (0.5)	3 (0.4)
顔面浮腫	0	1 (0.2)	1 (0.1)
びくびく感	0	1 (0.2)	1 (0.1)
発熱	1 (0.2)	0	1 (0.1)
肝胆道系障害	0	1 (0.2)	1 (0.1)
肝機能異常	0	1 (0.2)	1 (0.1)
感染症および寄生虫症	3 (0.7)	7 (1.7)	10 (1.2)
ヘルペス性状湿疹	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.
Subjects are counted once in each row, regardless of the number of events they may have had.

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=401) n (%)	UPA 30 mg QD (N=408) n (%)	Total (N=809) n (%)
感染症および寄生虫症 (Cont.)			
眼感染	1 (0.2)	0	1 (0.1)
B型肝炎	0	1 (0.2)	1 (0.1)
帯状疱疹	0	1 (0.2)	1 (0.1)
骨髄炎	0	1 (0.2)	1 (0.1)
咽頭膿瘍	0	1 (0.2)	1 (0.1)
咽頭扁桃炎	1 (0.2)	0	1 (0.1)
肺炎	0	1 (0.2)	1 (0.1)
肺結核	1 (0.2)	0	1 (0.1)
腎盂腎炎	0	1 (0.2)	1 (0.1)
敗血症	0	1 (0.2)	1 (0.1)
ブドウ球菌性敗血症	0	1 (0.2)	1 (0.1)
臨床検査	2 (0.5)	6 (1.5)	8 (1.0)
アラニンアミノトランスフェラーゼ増加	0	2 (0.5)	2 (0.2)
アスパラギン酸アミノトランスフェラーゼ増加	0	2 (0.5)	2 (0.2)
血中クレアチンホスホキナーゼ増加	0	2 (0.5)	2 (0.2)
心雑音	0	1 (0.2)	1 (0.1)
心電図QT間隔異常	1 (0.2)	0	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.
Subjects are counted once in each row, regardless of the number of events they may have had.

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=401) n (%)	UPA 30 mg QD (N=408) n (%)	Total (N=809) n (%)
臨床検査 (Cont.)			
ヘモグロビン減少	0	1 (0.2)	1 (0.1)
尿妊娠反応陽性	1 (0.2)	0	1 (0.1)
トランスアミナーゼ上昇	0	1 (0.2)	1 (0.1)
代謝および栄養障害	0	2 (0.5)	2 (0.2)
食欲減退	0	1 (0.2)	1 (0.1)
食欲亢進	0	1 (0.2)	1 (0.1)
筋骨格系および結合組織障害	0	2 (0.5)	2 (0.2)
背部痛	0	1 (0.2)	1 (0.1)
筋肉痛	0	1 (0.2)	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）	1 (0.2)	2 (0.5)	3 (0.4)
乳癌	1 (0.2)	0	1 (0.1)
胃癌	0	1 (0.2)	1 (0.1)
浸潤性乳管癌	0	1 (0.2)	1 (0.1)
神経系障害	2 (0.5)	1 (0.2)	3 (0.4)
注意力障害	1 (0.2)	0	1 (0.1)
浮動性めまい	1 (0.2)	0	1 (0.1)
頭痛	1 (0.2)	1 (0.2)	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.
Subjects are counted once in each row, regardless of the number of events they may have had.

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=401) n (%)	UPA 30 mg QD (N=408) n (%)	Total (N=809) n (%)
神経系障害 (Cont.)			
虚血性脳卒中	1 (0.2)	0	1 (0.1)
精神障害	2 (0.5)	0	2 (0.2)
うつ病	1 (0.2)	0	1 (0.1)
睡眠障害	1 (0.2)	0	1 (0.1)
皮膚および皮下組織障害	7 (1.7)	7 (1.7)	14 (1.7)
ざ瘡	1 (0.2)	2 (0.5)	3 (0.4)
アトピー性皮膚炎	4 (1.0)	1 (0.2)	5 (0.6)
湿疹	0	1 (0.2)	1 (0.1)
紅斑	0	1 (0.2)	1 (0.1)
類乾癬	0	1 (0.2)	1 (0.1)
光線過敏性反応	0	1 (0.2)	1 (0.1)
そう痒症	1 (0.2)	0	1 (0.1)
中毒性表皮壊死融解症	1 (0.2)	0	1 (0.1)
血管障害	1 (0.2)	0	1 (0.1)
深部静脈血栓症	1 (0.2)	0	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.
Subjects are counted once in each row, regardless of the number of events they may have had.

相互参照：M16-045 試験 CSR W52 Table 14.3　2.3.1

表 2.7.4.7-53. 投与 52 週時データカットオフまでの 100 人年あたりの治験薬の投与中止に至った有害事象（ALL_UPA_M 集団）：M16-045 試験

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=401) (PYS=490.9) Events (E/100PY)	UPA 30 mg QD (N=408) (PYS=501.0) Events (E/100PY)	Total (N=809) (PYS=991.9) Events (E/100PY)
Any adverse event	22 (4.5)	39 (7.8)	61 (6.1)
血液およびリンパ系障害	0	2 (0.4)	2 (0.2)
好中球減少症	0	2 (0.4)	2 (0.2)
心臓障害	0	1 (0.2)	1 (0.1)
心筋梗塞	0	1 (0.2)	1 (0.1)
先天性、家族性および遺伝性障害	1 (0.2)	0	1 (0.1)
ネザートン症候群	1 (0.2)	0	1 (0.1)
胃腸障害	0	1 (0.2)	1 (0.1)
鼓腸	0	1 (0.2)	1 (0.1)
一般・全身障害および投与部位の状態	1 (0.2)	2 (0.4)	3 (0.3)
顔面浮腫	0	1 (0.2)	1 (0.1)
びくびく感	0	1 (0.2)	1 (0.1)
発熱	1 (0.2)	0	1 (0.1)
肝胆道系障害	0	1 (0.2)	1 (0.1)
肝機能異常	0	1 (0.2)	1 (0.1)
感染症および寄生虫症	3 (0.6)	9 (1.8)	12 (1.2)
ヘルペス性状湿疹	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.

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=401) (PYS=490.9) Events (E/100PY)	UPA 30 mg QD (N=408) (PYS=501.0) Events (E/100PY)	Total (N=809) (PYS=991.9) Events (E/100PY)
感染症および寄生虫症 (Cont.)			
眼感染	1 (0.2)	0	1 (0.1)
B型肝炎	0	1 (0.2)	1 (0.1)
帯状疱疹	0	1 (0.2)	1 (0.1)
骨髄炎	0	1 (0.2)	1 (0.1)
咽頭膿瘍	0	1 (0.2)	1 (0.1)
咽頭扁桃炎	1 (0.2)	0	1 (0.1)
肺炎	0	1 (0.2)	1 (0.1)
肺結核	1 (0.2)	0	1 (0.1)
腎盂腎炎	0	1 (0.2)	1 (0.1)
敗血症	0	1 (0.2)	1 (0.1)
ブドウ球菌性敗血症	0	1 (0.2)	1 (0.1)
臨床検査	2 (0.4)	9 (1.8)	11 (1.1)
アラニンアミノトランスフェラーゼ増加	0	2 (0.4)	2 (0.2)
アスパラギン酸アミノトランスフェラーゼ増加	0	2 (0.4)	2 (0.2)
血中クレアチンホスホキナーゼ増加	0	2 (0.4)	2 (0.2)
心雑音	0	1 (0.2)	1 (0.1)
心電図QT間隔異常	1 (0.2)	0	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.

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=401) (PYS=490.9) Events (E/100PY)	UPA 30 mg QD (N=408) (PYS=501.0) Events (E/100PY)	Total (N=809) (PYS=991.9) Events (E/100PY)
臨床検査 (Cont.)			
ヘモグロビン減少	0	1 (0.2)	1 (0.1)
尿妊娠反応陽性	1 (0.2)	0	1 (0.1)
トランスアミナーゼ上昇	0	1 (0.2)	1 (0.1)
代謝および栄養障害	0	2 (0.4)	2 (0.2)
食欲減退	0	1 (0.2)	1 (0.1)
食欲亢進	0	1 (0.2)	1 (0.1)
筋骨格系および結合組織障害	0	2 (0.4)	2 (0.2)
背部痛	0	1 (0.2)	1 (0.1)
筋肉痛	0	1 (0.2)	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）	1 (0.2)	2 (0.4)	3 (0.3)
乳癌	1 (0.2)	0	1 (0.1)
胃癌	0	1 (0.2)	1 (0.1)
浸潤性乳管癌	0	1 (0.2)	1 (0.1)
神経系障害	4 (0.8)	1 (0.2)	5 (0.5)
注意力障害	1 (0.2)	0	1 (0.1)
浮動性めまい	1 (0.2)	0	1 (0.1)
頭痛	1 (0.2)	1 (0.2)	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.

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=401) (PYS=490.9) Events (E/100PY)	UPA 30 mg QD (N=408) (PYS=501.0) Events (E/100PY)	Total (N=809) (PYS=991.9) Events (E/100PY)
神経系障害 (Cont.)			
虚血性脳卒中	1 (0.2)	0	1 (0.1)
精神障害	2 (0.4)	0	2 (0.2)
うつ病	1 (0.2)	0	1 (0.1)
睡眠障害	1 (0.2)	0	1 (0.1)
皮膚および皮下組織障害	7 (1.4)	7 (1.4)	14 (1.4)
ざ瘡	1 (0.2)	2 (0.4)	3 (0.3)
アトピー性皮膚炎	4 (0.8)	1 (0.2)	5 (0.5)
湿疹	0	1 (0.2)	1 (0.1)
紅斑	0	1 (0.2)	1 (0.1)
類乾癬	0	1 (0.2)	1 (0.1)
光線過敏性反応	0	1 (0.2)	1 (0.1)
そう痒症	1 (0.2)	0	1 (0.1)
中毒性表皮壊死融解症	1 (0.2)	0	1 (0.1)
血管障害	1 (0.2)	0	1 (0.1)
深部静脈血栓症	1 (0.2)	0	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.

相互参照：M16-045 試験 CSR W52 Table 14.3　2.3.2

表 2.7.4.7-54. 投与 16 週時までの治験薬の投与中止に至った有害事象（Safety_DB_M 集団）：M16-047 試験

MedDRA 22.1 System Organ Class Preferred Term	Placebo + TCS (N=303) n (%)	Active UPA 15 mg QD + TCS (N=300) n (%)	Active UPA 30 mg QD + TCS (N=297) n (%)	Total (N=597) n (%)
Any adverse event	7 (2.3)	4 (1.3)	4 (1.3)	8 (1.3)
血液およびリンパ系障害	0	0	1 (0.3)	1 (0.2)
好中球減少症	0	0	1 (0.3)	1 (0.2)
胃腸障害	0	1 (0.3)	0	1 (0.2)
上腹部痛	0	1 (0.3)	0	1 (0.2)
肝胆道系障害	0	1 (0.3)	0	1 (0.2)
肝機能異常	0	1 (0.3)	0	1 (0.2)
感染症および寄生虫症	2 (0.7)	0	1 (0.3)	1 (0.2)
心内膜炎	1 (0.3)	0	0	0
ヘルペス眼感染	0	0	1 (0.3)	1 (0.2)
肺炎	1 (0.3)	0	0	0
ブドウ球菌性敗血症	1 (0.3)	0	0	0
臨床検査	2 (0.7)	0	0	0
血中クレアチンホスホキナーゼ増加	1 (0.3)	0	0	0
体重増加	1 (0.3)	0	0	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	0	1 (0.3)	1 (0.2)
結腸腺癌	0	0	1 (0.3)	1 (0.2)

Note: Treatment-emergent adverse events in DB Period are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or no more than 30 days after the last dose of study drug in DB Period, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.

MedDRA 22.1 System Organ Class Preferred Term	Placebo + TCS (N=303) n (%)	Active UPA 15 mg QD + TCS (N=300) n (%)	Active UPA 30 mg QD + TCS (N=297) n (%)	Total (N=597) n (%)
精神障害	0	0	1 (0.3)	1 (0.2)
混合性不安抑うつ障害	0	0	1 (0.3)	1 (0.2)
呼吸器、胸郭および縦隔障害	1 (0.3)	0	0	0
急性呼吸不全	1 (0.3)	0	0	0
皮膚および皮下組織障害	3 (1.0)	2 (0.7)	0	2 (0.3)
アトピー性皮膚炎	2 (0.7)	2 (0.7)	0	2 (0.3)
全身性剥脱性皮膚炎	1 (0.3)	0	0	0

Note: Treatment-emergent adverse events in DB Period are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or no more than 30 days after the last dose of study drug in DB Period, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.

相互参照：M16-047 試験 CSR W16 Table 14.3　2.3.1

表 2.7.4.7-55. 投与 52 週時データカットオフまでの治験薬の投与中止に至った有害事象（ALL_UPA_M 集団）：M16-047 試験

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	18 (4.1)	16 (3.7)	34 (3.9)
血液およびリンパ系障害	0	1 (0.2)	1 (0.1)
好中球減少症	0	1 (0.2)	1 (0.1)
胃腸障害	1 (0.2)	0	1 (0.1)
上腹部痛	1 (0.2)	0	1 (0.1)
一般・全身障害および投与部位の状態	1 (0.2)	0	1 (0.1)
倦怠感	1 (0.2)	0	1 (0.1)
肝胆道系障害	1 (0.2)	0	1 (0.1)
肝機能異常	1 (0.2)	0	1 (0.1)
感染症および寄生虫症	6 (1.4)	6 (1.4)	12 (1.4)
気管支炎	0	1 (0.2)	1 (0.1)
ヘルペス性状湿疹	0	1 (0.2)	1 (0.1)
毛包炎	1 (0.2)	0	1 (0.1)
ヘルペス眼感染	0	1 (0.2)	1 (0.1)
単純ヘルペス	0	2 (0.5)	2 (0.2)
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)

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

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.)			
膿痂疹	2 (0.5)	0	2 (0.2)
カポジ水痘様発疹	0	1 (0.2)	1 (0.1)
肺炎	1 (0.2)	0	1 (0.1)
ライノウイルス感染	0	1 (0.2)	1 (0.1)
尿路感染	1 (0.2)	0	1 (0.1)
臨床検査	2 (0.5)	2 (0.5)	4 (0.5)
心電図QT間隔異常	1 (0.2)	0	1 (0.1)
ヘモグロビン減少	0	1 (0.2)	1 (0.1)
体重増加	1 (0.2)	1 (0.2)	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）	1 (0.2)	1 (0.2)	2 (0.2)
結腸腺癌	0	1 (0.2)	1 (0.1)
口腔内扁平上皮癌	1 (0.2)	0	1 (0.1)
神経系障害	1 (0.2)	2 (0.5)	3 (0.3)
脳血管発作	0	1 (0.2)	1 (0.1)
多発性硬化症	0	1 (0.2)	1 (0.1)
くも膜下出血	1 (0.2)	0	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.
Subjects are counted once in each row, regardless of the number of events they may have had.

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	0	1 (0.2)	1 (0.1)
混合性不安抑うつ障害	0	1 (0.2)	1 (0.1)
呼吸器、胸郭および縦隔障害	2 (0.5)	0	2 (0.2)
呼吸困難	1 (0.2)	0	1 (0.1)
肺塞栓症	1 (0.2)	0	1 (0.1)
皮膚および皮下組織障害	5 (1.1)	5 (1.1)	10 (1.1)
ざ瘡	0	1 (0.2)	1 (0.1)
アレルギー性皮膚炎	0	1 (0.2)	1 (0.1)
アトピー性皮膚炎	5 (1.1)	2 (0.5)	7 (0.8)
丘疹性皮疹	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.
Subjects are counted once in each row, regardless of the number of events they may have had.

相互参照：M16-047 試験 CSR W52 Table 14.3　2.3.1

表 2.7.4.7-56. 投与 52 週時データカットオフまでの 100 人年あたりの治験薬の投与中止に至った有害事象（ALL_UPA_M 集団）：M16-047 試験

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	20 (3.9)	20 (3.8)	40 (3.8)
血液およびリンパ系障害	0	1 (0.2)	1 (<0.1)
好中球減少症	0	1 (0.2)	1 (<0.1)
胃腸障害	1 (0.2)	0	1 (<0.1)
上腹部痛	1 (0.2)	0	1 (<0.1)
一般・全身障害および投与部位の状態	1 (0.2)	0	1 (<0.1)
倦怠感	1 (0.2)	0	1 (<0.1)
肝胆道系障害	1 (0.2)	0	1 (<0.1)
肝機能異常	1 (0.2)	0	1 (<0.1)
感染症および寄生虫症	6 (1.2)	8 (1.5)	14 (1.3)
気管支炎	0	1 (0.2)	1 (<0.1)
ヘルペス性状湿疹	0	1 (0.2)	1 (<0.1)
毛包炎	1 (0.2)	0	1 (<0.1)
ヘルペス眼感染	0	1 (0.2)	1 (<0.1)
単純ヘルペス	0	2 (0.4)	2 (0.2)
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)

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.

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.)			
膿痂疹	2 (0.4)	0	2 (0.2)
カポジ水痘様発疹	0	1 (0.2)	1 (<0.1)
肺炎	1 (0.2)	0	1 (<0.1)
ライノウイルス感染	0	1 (0.2)	1 (<0.1)
尿路感染	1 (0.2)	0	1 (<0.1)
臨床検査	2 (0.4)	2 (0.4)	4 (0.4)
心電図QT間隔異常	1 (0.2)	0	1 (<0.1)
ヘモグロビン減少	0	1 (0.2)	1 (<0.1)
体重増加	1 (0.2)	1 (0.2)	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）	1 (0.2)	1 (0.2)	2 (0.2)
結腸腺癌	0	1 (0.2)	1 (<0.1)
口腔内扁平上皮癌	1 (0.2)	0	1 (<0.1)
神経系障害	1 (0.2)	2 (0.4)	3 (0.3)
脳血管発作	0	1 (0.2)	1 (<0.1)
多発性硬化症	0	1 (0.2)	1 (<0.1)
くも膜下出血	1 (0.2)	0	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.

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)
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)
呼吸器、胸郭および縦隔障害	2 (0.4)	0	2 (0.2)
呼吸困難	1 (0.2)	0	1 (<0.1)
肺塞栓症	1 (0.2)	0	1 (<0.1)
皮膚および皮下組織障害	5 (1.0)	5 (0.9)	10 (1.0)
ざ瘡	0	1 (0.2)	1 (<0.1)
アレルギー性皮膚炎	0	1 (0.2)	1 (<0.1)
アトピー性皮膚炎	5 (1.0)	2 (0.4)	7 (0.7)
丘疹性皮疹	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.

相互参照：M16-047 試験 CSR W52 Table 14.3　2.3.2

表 2.7.4.7-57. 投与 16 週時までの治験薬の投与中止に至った有害事象（Safety_DB 集団）：M17-377 試験

MedDRA 22.1 System Organ Class Preferred Term	Placebo (N=90) n (%)	----------Active---------- UPA 15 mg QD (N=91) n (%)	UPA 30 mg QD (N=91) n (%)	UPA Total (N=182) n (%)
Any adverse event	1 (1.1)	2 (2.2)	1 (1.1)	3 (1.6)
一般・全身障害および投与部位の状態	0	0	1 (1.1)	1 (0.5)
末梢性浮腫	0	0	1 (1.1)	1 (0.5)
感染症および寄生虫症	0	1 (1.1)	0	1 (0.5)
カポジ水痘様発疹	0	1 (1.1)	0	1 (0.5)
神経系障害	0	1 (1.1)	0	1 (0.5)
小脳出血	0	1 (1.1)	0	1 (0.5)
皮膚および皮下組織障害	1 (1.1)	0	0	0
アトピー性皮膚炎	1 (1.1)	0	0	0

AE = adverse event; BE = blind extension; DB = double blind; MedDRA = Medical Dictionary for Regulatory Activities; PBO = placebo; QD = once daily; TEAE = treatment emergent adverse event; UPA = upadacitinib.

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.

相互参照：M17-377 試験 CSR W24 Table 14.3 2.3.1

表 2.7.4.7-58. 投与 24 週時データカットオフまでの治験薬の投与中止に至った有害事象（ALL_UPA 集団）：M17-377 試験

MedDRA 22.1 System Organ Class Preferred Term	----------Active---------- UPA 15 mg QD (N=133) n (%)	UPA 30 mg QD (N=136) n (%)	UPA Total (N=269) n (%)
Any adverse event	4 (3.0)	1 (0.7)	5 (1.9)
一般・全身障害および投与部位の状態	0	1 (0.7)	1 (0.4)
末梢性浮腫	0	1 (0.7)	1 (0.4)
感染症および寄生虫症	2 (1.5)	0	2 (0.7)
カポジ水痘様発疹	1 (0.8)	0	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)
神経系障害	1 (0.8)	0	1 (0.4)
小脳出血	1 (0.8)	0	1 (0.4)
皮膚および皮下組織障害	1 (0.8)	0	1 (0.4)
アトピー性皮膚炎	1 (0.8)	0	1 (0.4)

AE = adverse event; MedDRA = Medical Dictionary for Regulatory Activities; QD = once daily; TEAE = treatment-emergent adverse event; UPA = upadacitinib.

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.

相互参照：M17-377 試験 CSR W24 Table 14.3 2.3.2

表 2.7.4.7-59.　投与 24 週時データカットオフまでの 100 人年あたりの治験薬の投与中止に至った有害事象（ALL_UPA 集団）：M17-377 試験

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)
Any adverse event	4 (4.8)	1 (1.2)	5 (3.0)
一般・全身障害および投与部位の状態	0	1 (1.2)	1 (0.6)
末梢性浮腫	0	1 (1.2)	1 (0.6)
感染症および寄生虫症	2 (2.4)	0	2 (1.2)
カポジ水痘様発疹	1 (1.2)	0	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)
神経系障害	1 (1.2)	0	1 (0.6)
小脳出血	1 (1.2)	0	1 (0.6)
皮膚および皮下組織障害	1 (1.2)	0	1 (0.6)
アトピー性皮膚炎	1 (1.2)	0	1 (0.6)

AE = adverse event; E/100PY = events per 100 patient-years; MedDRA = Medical Dictionary for Regulatory Activities; PY = patient-years; QD = once daily; SAE = serious adverse event; TEAE = treatment emergent adverse event; UPA = upadacitinib.

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.

相互参照：M17-377 試験 CSR W24 Table 14.3　2.3.3

表 2.7.4.7-60. 投与 52 週時データカットオフまでの治験薬の投与中止に至った有害事象（ALL_UPA 集団）：M17-377 試験

MedDRA 22.1 System Organ Class Preferred Term	----------Active---------- UPA 15 mg QD (N=133) n (%)	UPA 30 mg QD (N=136) n (%)	UPA Total (N=269) n (%)
Any adverse event	4 (3.0)	3 (2.2)	7 (2.6)
一般・全身障害および投与部位の状態	0	1 (0.7)	1 (0.4)
末梢性浮腫	0	1 (0.7)	1 (0.4)
感染症および寄生虫症	2 (1.5)	0	2 (0.7)
カポジ水痘様発疹	1 (0.8)	0	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)
臨床検査	0	2 (1.5)	2 (0.7)
アラニンアミノトランスフェラーゼ増加	0	1 (0.7)	1 (0.4)
リンパ球形態異常	0	1 (0.7)	1 (0.4)
神経系障害	1 (0.8)	0	1 (0.4)
小脳出血	1 (0.8)	0	1 (0.4)
皮膚および皮下組織障害	1 (0.8)	0	1 (0.4)
アトピー性皮膚炎	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.

相互参照：M17-377 試験 CSR W52 Table 14.3　2.3.2

表 2.7.4.7-61. 投与 52 週時データカットオフまでの 100 人年あたりの治験薬の投与中止に至った有害事象（ALL_UPA 集団）：M17-377 試験

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)
Any adverse event	4 (2.6)	3 (2.0)	7 (2.3)
一般・全身障害および投与部位の状態	0	1 (0.7)	1 (0.3)
末梢性浮腫	0	1 (0.7)	1 (0.3)
感染症および寄生虫症	2 (1.3)	0	2 (0.7)
カポジ水痘様発疹	1 (0.7)	0	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)
臨床検査	0	2 (1.3)	2 (0.7)
アラニンアミノトランスフェラーゼ増加	0	1 (0.7)	1 (0.3)
リンパ球形態異常	0	1 (0.7)	1 (0.3)
神経系障害	1 (0.7)	0	1 (0.3)
小脳出血	1 (0.7)	0	1 (0.3)
皮膚および皮下組織障害	1 (0.7)	0	1 (0.3)
アトピー性皮膚炎	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.

相互参照：M17-377 試験 CSR W52 Table 14.3　2.3.3

表 2.7.4.7-62. 第 1 ピリオド（投与 16 週時まで）の治験薬の投与中止に至った有害事象（Safety 1 集団）：M16-048 試験

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	PLACEBO (N=40) n (%)	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=42) n (%)	TOTAL (N=126) n (%)
ANY ADVERSE EVENT	3 (7.5)	4 (9.5)	2 (4.8)	4 (9.5)	10 (7.9)
一般・全身障害および投与部位の状態					
顔面浮腫	0	0	0	1 (2.4)	1 (0.8)
疼痛	0	0	0	1 (2.4)	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	2 (4.8)	2 (1.6)
感染症および寄生虫症					
膿痂疹	0	0	0	1 (2.4)	1 (0.8)
皮膚感染	0	1 (2.4)	0	0	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (2.4)	0	1 (2.4)	2 (1.6)
代謝および栄養障害					
低ナトリウム血症	1 (2.5)	0	0	0	0
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.5)	0	0	0	0
生殖系および乳房障害					
生殖器病変	1 (2.5)	0	0	0	0
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.5)	0	0	0	0
皮膚および皮下組織障害					
アトピー性皮膚炎	1 (2.5)	4 (9.5)	1 (2.4)	2 (4.8)	7 (5.6)
斑状丘疹状皮疹	0	0	1 (2.4)	0	1 (0.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	PLACEBO (N=40) n (%)	----------UPA---------- 7.5 MG QD (N=42) n (%)	15 MG QD (N=42) n (%)	30 MG QD (N=42) n (%)	TOTAL (N=126) n (%)
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.5)	4 (9.5)	2 (4.8)	2 (4.8)	8 (6.3)

NOTE: TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS ANY ADVERSE EVENT WITH AN ONSET DATE ON OR AFTER THE FIRST DOSE OF STUDY DRUG IN PERIOD 1 AND PRIOR TO THE FIRST DOSE OF STUDY DRUG IN PERIOD 2 OR UP TO 30 DAYS AFTER THE LAST DOSE OF STUDY DRUG IF SUBJECT DISCONTINUED STUDY DRUG PREMATURELY FROM PERIOD 1 OF THE STUDY.
THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.

相互参照：M16-048 試験 CSR Table 14.3__2.2.1

表 2.7.4.7-63. 全期間（第 1 ピリオド及び第 2 ピリオド）の治験薬の投与中止に至った有害事象（Safety 1 集団及び Safety 2 集団）：M16-048 試験

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
ANY ADVERSE EVENT	4 (9.5)	2 (4.8)	10 (8.8)
心臓障害			
心膜炎	0	0	1 (0.9)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	1 (0.9)
胃腸障害			
食道瘻	0	0	1 (0.9)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	1 (0.9)
一般・全身障害および投与部位の状態			
顔面浮腫	0	0	1 (0.9)
末梢性浮腫	0	0	1 (0.9)
疼痛	0	0	1 (0.9)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	3 (2.6)
感染症および寄生虫症			
膿痂疹	0	0	1 (0.9)
敗血症	0	0	1 (0.9)
皮膚感染	1 (2.4)	0	0
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.4)	0	2 (1.8)

臨床検査

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
ヘモグロビン減少	0	0	1 (0.9)
SUBJECTS WITH ONE OR MORE EVENTS	0	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）			
菌状息肉症	0	0	1 (0.9)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	1 (0.9)
生殖系および乳房障害			
勃起不全	0	0	1 (0.9)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	1 (0.9)
皮膚および皮下組織障害			
アトピー性皮膚炎	4 (9.5)	1 (2.4)	3 (2.6)
斑状丘疹状皮疹	0	1 (2.4)	0
SUBJECTS WITH ONE OR MORE EVENTS	4 (9.5)	2 (4.8)	3 (2.6)

NOTE: TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS ANY ADVERSE EVENT WITH AN ONSET DATE ON OR AFTER THE FIRST DOSE OF UPA AND UP TO 30 DAYS AFTER THE LAST DOSE OF UPA. ANY ADVERSE EVENT WITH AN ONSET DATE ON OR AFTER THE FIRST DOSE OF UPA 30 MG RESCUE THERAPHY WILL BE COUNTED INTO UPA 30 MG GROUP. A PATIENT RECEIVING RESCUE THERAPHY AFTER UPA 7.5 MG/15 MG TREATMENT WILL BE COUNTED IN THE DENOMINATORS OF BOTH 7.5 MG/15 MG AND 30 MG DOSE GROUPS.
THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WITHIN EACH TREATMENT GROUP WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.

相互参照：M16-048 試験 CSR Table 14.3　2.2.2

表 2.7.4.7-64. 全期間（第 1 ピリオド及び第 2 ピリオド）の 100 人年あたりの治験薬の投与中止に至った有害事象（Safety 1 集団及び Safety 2 集団）：M16-048 試験

	UPA		
SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
ANY ADVERSE EVENT	5 (32.9)	2 (9.7)	13 (10.0)
心臓障害			
心膜炎	0	0	1 (0.8)
TOTAL EVENTS	0	0	1 (0.8)
胃腸障害			
食道瘻	0	0	1 (0.8)
TOTAL EVENTS	0	0	1 (0.8)
一般・全身障害および投与部位の状態			
顔面浮腫	0	0	1 (0.8)
末梢性浮腫	0	0	1 (0.8)
疼痛	0	0	1 (0.8)
TOTAL EVENTS	0	0	3 (2.3)
感染症および寄生虫症			
膿痂疹	0	0	1 (0.8)
敗血症	0	0	1 (0.8)
皮膚感染	1 (6.6)	0	0
TOTAL EVENTS	1 (6.6)	0	2 (1.5)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
臨床検査			
ヘモグロビン減少	0	0	1 (0.8)
TOTAL EVENTS	0	0	1 (0.8)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）			
菌状息肉症	0	0	1 (0.8)
TOTAL EVENTS	0	0	1 (0.8)
生殖系および乳房障害			
勃起不全	0	0	1 (0.8)
TOTAL EVENTS	0	0	1 (0.8)
皮膚および皮下組織障害			
アトピー性皮膚炎	4 (26.3)	1 (4.8)	3 (2.3)
斑状丘疹状皮疹	0	1 (4.8)	0
TOTAL EVENTS	4 (26.3)	2 (9.7)	3 (2.3)

NOTE: TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS ANY ADVERSE EVENT WITH AN ONSET DATE ON OR AFTER THE FIRST DOSE OF UPA AND UP TO 30 DAYS AFTER THE LAST DOSE OF UPA. ANY ADVERSE EVENT WITH AN ONSET DATE ON OR AFTER THE FIRST DOSE OF UPA 30 MG RESCUE THERAPHY WILL BE COUNTED INTO UPA 30 MG GROUP. A PATIENT RECEIVING RESCUE THERAPHY AFTER UPA 7.5 MG/15 MG TREATMENT WILL BE COUNTED IN THE DENOMINATORS OF BOTH 7.5 MG/15 MG AND 30 MG DOSE GROUPS. E/100PY = EVENTS PER 100 PATIENT-YEARS.

相互参照：M16-048 試験 CSR Table 14.3 2.2.3

表 2.7.4.7-65. プラセボ対照併合解析集団（16 週，M16-045 試験，M16-047 試験，M17-377 試験，M16-048 試験及び M18-891 試験）の日和見感染（結核及び帯状疱疹を除く）の発現割合（全体集団及び日本人集団）

	Japan			Overall		
		Active			Active	
MedDRA 22.1 System Organ Class Preferred Term	Placebo (N=124) n (%)	UPA 15 mg QD (N=125) n (%)	UPA 30 mg QD (N=127) n (%)	Placebo (N=992) n (%)	UPA 15 mg QD (N=990) n (%)	UPA 30 mg QD (N=997) n (%)
Any adverse event	1 (0.8)	4 (3.2)	1 (0.8)	4 (0.4)	9 (0.9)	8 (0.8)
感染症および寄生虫症	1 (0.8)	4 (3.2)	1 (0.8)	4 (0.4)	9 (0.9)	8 (0.8)
ヘルペス性状湿疹	0	0	0	2 (0.2)	5 (0.5)	5 (0.5)
カポジ水痘様発疹	1 (0.8)	4 (3.2)	1 (0.8)	2 (0.2)	4 (0.4)	3 (0.3)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or up to 30 days after the last dose of study drug in DB Period, whichever occurs first.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total.
A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
Subjects are counted once in each row, regardless of the number of events they may have had.

相互参照：ISS Table 2.4　1.3.17.3

表 2.7.4.7-66. プラセボ対照併合解析集団（16 週，M16-045 試験，M16-047 試験，M17-377 試験，M16-048 試験及び M18-891 試験）の青少年被験者及び成人被験者の日和見感染（結核及び帯状疱疹を除く）の発現割合（全体集団及び日本人集団）

Subgroup: Adolescent

MedDRA 22.1 System Organ Class Preferred Term	Japan Placebo (N=10) n (%)	Japan Active UPA 15 mg QD (N=11) n (%)	Japan Active UPA 30 mg QD (N=12) n (%)	Overall Placebo (N=124) n (%)	Overall Active UPA 15 mg QD (N=124) n (%)	Overall Active UPA 30 mg QD (N=124) n (%)
Any adverse event	0	1 (9.1)	0	0	1 (0.8)	0
感染症および寄生虫症	0	1 (9.1)	0	0	1 (0.8)	0
カポジ水痘様発疹	0	1 (9.1)	0	0	1 (0.8)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or up to 30 days after the last dose of study drug in DB Period, whichever occurs first.
Subjects are counted once in each row, regardless of the number of events they may have had.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total.
A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

Subgroup: Adult

MedDRA 22.1 System Organ Class Preferred Term	Japan Placebo (N=114) n (%)	Japan Active UPA 15 mg QD (N=114) n (%)	Japan Active UPA 30 mg QD (N=115) n (%)	Overall Placebo (N=868) n (%)	Overall Active UPA 15 mg QD (N=866) n (%)	Overall Active UPA 30 mg QD (N=873) n (%)
Any adverse event	1 (0.9)	3 (2.6)	1 (0.9)	4 (0.5)	8 (0.9)	8 (0.9)
感染症および寄生虫症	1 (0.9)	3 (2.6)	1 (0.9)	4 (0.5)	8 (0.9)	8 (0.9)
ヘルペス性状湿疹	0	0	0	2 (0.2)	5 (0.6)	5 (0.6)
カポジ水痘様発疹	1 (0.9)	3 (2.6)	1 (0.9)	2 (0.2)	3 (0.3)	3 (0.3)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or up to 30 days after the last dose of study drug in DB Period, whichever occurs first.
Subjects are counted once in each row, regardless of the number of events they may have had.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total.
A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

相互参照：ISS Table 2.4　1.6.7.3

表 2.7.4.7-67. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の 100 人年あたりの日和見感染（結核及び帯状疱疹を除く）の発現率（全体集団及び日本人集団）

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=135.8) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=137.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1371) (PYS=955.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1378) (PYS=974.2) Events (E/100PY)
Any adverse event	7 (5.2)	8 (5.8)	23 (2.4)	22 (2.3)
感染症および寄生虫症	7 (5.2)	8 (5.8)	23 (2.4)	22 (2.3)
ヘルペス性状湿疹	0	0	16 (1.7)	11 (1.1)
カポジ水痘様発疹	6 (4.4)	8 (5.8)	6 (0.6)	11 (1.1)
ニューモシスチス・イロベチイ肺炎	1 (0.7)	0	1 (0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：ISS Table 2.4　2.4.1.3

表 2.7.4.7-68. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の青少年被験者及び成人被験者の 100 人年あたりの日和見感染（結核及び帯状疱疹を除く）の発現率（全体集団及び日本人集団）

Subgroup: Adolescent

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=16) (PYS=11.7) Events (E/100PY)	Japan UPA 30 mg QD (N=16) (PYS=11.3) Events (E/100PY)	Overall UPA 15 mg QD (N=181) (PYS=132.5) Events (E/100PY)	Overall UPA 30 mg QD (N=180) (PYS=134.1) Events (E/100PY)
Any adverse event	1 (8.6)	0	2 (1.5)	1 (0.7)
感染症および寄生虫症	1 (8.6)	0	2 (1.5)	1 (0.7)
ヘルペス性状湿疹	0	0	1 (0.8)	1 (0.7)
カポジ水痘様発疹	1 (8.6)	0	1 (0.8)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

Subgroup: Adult

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=161) (PYS=124.1) Events (E/100PY)	Japan UPA 30 mg QD (N=165) (PYS=126.0) Events (E/100PY)	Overall UPA 15 mg QD (N=1190) (PYS=822.4) Events (E/100PY)	Overall UPA 30 mg QD (N=1198) (PYS=840.1) Events (E/100PY)
Any adverse event	6 (4.8)	8 (6.3)	21 (2.6)	21 (2.5)
感染症および寄生虫症	6 (4.8)	8 (6.3)	21 (2.6)	21 (2.5)
ヘルペス性状湿疹	0	0	15 (1.8)	10 (1.2)
カポジ水痘様発疹	5 (4.0)	8 (6.3)	5 (0.6)	11 (1.3)
ニューモシスチス・イロベチイ肺炎	1 (0.8)	0	1 (0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：ISS Table 2.4　2.9.5.3

表 2.7.4.7-69. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の 100 人年あたりの日和見感染（結核及び帯状疱疹を除く）の発現率（全体集団及び日本人集団，更新時）

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=225.5) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=228.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1372) (PYS=1407.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1380) (PYS=1446.5) Events (E/100PY)
Any adverse event	13 (5.8)	10 (4.4)	33 (2.3)	37 (2.6)
感染症および寄生虫症	13 (5.8)	10 (4.4)	33 (2.3)	37 (2.6)
ヘルペス性状湿疹	0	0	20 (1.4)	20 (1.4)
カポジ水痘様発疹	12 (5.3)	10 (4.4)	12 (0.9)	16 (1.1)
食道カンジダ症	0	0	0	1 (<0.1)
ニューモシスチス・イロベチイ肺炎	1 (0.4)	0	1 (<0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：Updated ISS Table 2.4　2.4.1.3

表 2.7.4.7-70. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の青少年被験者及び成人被験者の 100 人年あたりの日和見感染（結核及び帯状疱疹を除く）の発現率（全体集団及び日本人集団，更新時）

	Japan		Overall	
MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=16) (PYS=19.9) Events (E/100PY)	UPA 30 mg QD (N=16) (PYS=18.3) Events (E/100PY)	UPA 15 mg QD (N=181) (PYS=194.3) Events (E/100PY)	UPA 30 mg QD (N=180) (PYS=197.0) Events (E/100PY)
Subgroup: Adolescent				
Any adverse event	1 (5.0)	0	2 (1.0)	1 (0.5)
感染症および寄生虫症	1 (5.0)	0	2 (1.0)	1 (0.5)
ヘルペス性状湿疹	0	0	1 (0.5)	1 (0.5)
カポジ水痘様発疹	1 (5.0)	0	1 (0.5)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=161) (PYS=205.6) Events (E/100PY)	Japan UPA 30 mg QD (N=165) (PYS=210.0) Events (E/100PY)	Overall UPA 15 mg QD (N=1191) (PYS=1212.7) Events (E/100PY)	Overall UPA 30 mg QD (N=1200) (PYS=1249.5) Events (E/100PY)
Subgroup: Adult				
Any adverse event	12 (5.8)	10 (4.8)	31 (2.6)	36 (2.9)
感染症および寄生虫症	12 (5.8)	10 (4.8)	31 (2.6)	36 (2.9)
ヘルペス性状湿疹	0	0	19 (1.6)	19 (1.5)
カポジ水痘様発疹	11 (5.3)	10 (4.8)	11 (0.9)	16 (1.3)
食道カンジダ症	0	0	0	1 (<0.1)
ニューモシスチス・イロベチイ肺炎	1 (0.5)	0	1 (<0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：Updated ISS Table 2.4　2.9.5.3

表 2.7.4.7-71. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の 100 人年あたりの活動性結核の発現率（全体集団及び日本人集団）

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=135.8) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=137.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1371) (PYS=955.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1378) (PYS=974.2) Events (E/100PY)
Any adverse event	0	0	1 (0.1)	1 (0.1)
感染症および寄生虫症	0	0	1 (0.1)	1 (0.1)
肺結核	0	0	1 (0.1)	0
結核	0	0	0	1 (0.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：ISS Table 2.4　2.4.1.17

表 2.7.4.7-72. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の青少年被験者及び成人被験者の 100 人年あたりの活動性結核の発現率（全体集団及び日本人集団）

Subgroup: Adolescent

	Japan		Overall	
MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=16) (PYS=11.7) Events (E/100PY)	UPA 30 mg QD (N=16) (PYS=11.3) Events (E/100PY)	UPA 15 mg QD (N=181) (PYS=132.5) Events (E/100PY)	UPA 30 mg QD (N=180) (PYS=134.1) Events (E/100PY)
Any adverse event	0	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

Subgroup: Adult

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=161) (PYS=124.1) Events (E/100PY)	Japan UPA 30 mg QD (N=165) (PYS=126.0) Events (E/100PY)	Overall UPA 15 mg QD (N=1190) (PYS=822.4) Events (E/100PY)	Overall UPA 30 mg QD (N=1198) (PYS=840.1) Events (E/100PY)
Any adverse event	0	0	1 (0.1)	1 (0.1)
感染症および寄生虫症	0	0	1 (0.1)	1 (0.1)
肺結核	0	0	1 (0.1)	0
結核	0	0	0	1 (0.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：ISS Table 2.4　2.9.5.17

表 2.7.4.7-73. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の 100 人年あたりの活動性結核の発現率（全体集団及び日本人集団，更新時）

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=225.5) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=228.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1372) (PYS=1407.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1380) (PYS=1446.5) Events (E/100PY)
Any adverse event	0	0	1 (<0.1)	1 (<0.1)
感染症および寄生虫症	0	0	1 (<0.1)	1 (<0.1)
肺結核	0	0	1 (<0.1)	0
結核	0	0	0	1 (<0.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：Updated ISS Table 2.4　2.4.1.17

表 2.7.4.7-74. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の青少年被験者及び成人被験者の 100 人年あたりの活動性結核の発現率（全体集団及び日本人集団，更新時）

	Japan		Overall	
MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=16) (PYS=19.9) Events (E/100PY)	UPA 30 mg QD (N=16) (PYS=18.3) Events (E/100PY)	UPA 15 mg QD (N=181) (PYS=194.3) Events (E/100PY)	UPA 30 mg QD (N=180) (PYS=197.0) Events (E/100PY)
Subgroup: Adolescent				
Any adverse event	0	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=161) (PYS=205.6) Events (E/100PY)	Japan UPA 30 mg QD (N=165) (PYS=210.0) Events (E/100PY)	Overall UPA 15 mg QD (N=1191) (PYS=1212.7) Events (E/100PY)	Overall UPA 30 mg QD (N=1200) (PYS=1249.5) Events (E/100PY)
Subgroup: Adult				
Any adverse event	0	0	1 (<0.1)	1 (<0.1)
感染症および寄生虫症	0	0	1 (<0.1)	1 (<0.1)
肺結核	0	0	1 (<0.1)	0
結核	0	0	0	1 (<0.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：Updated ISS Table 2.4　2.9.5.17

表 2.7.4.7-75. プラセボ対照併合解析集団（16 週，M16-045 試験，M16-047 試験，M17-377 試験，M16-048 試験及び M18-891 試験）の薬剤に関連する肝障害の発現割合（全体集団及び日本人集団）

	Japan			Overall		
		Active			Active	
MedDRA 22.1 System Organ Class Preferred Term	Placebo (N=124) n (%)	UPA 15 mg QD (N=125) n (%)	UPA 30 mg QD (N=127) n (%)	Placebo (N=992) n (%)	UPA 15 mg QD (N=990) n (%)	UPA 30 mg QD (N=997) n (%)
Any adverse event	0	1 (0.8)	2 (1.6)	12 (1.2)	16 (1.6)	16 (1.6)
肝胆道系障害	0	0	0	1 (0.1)	2 (0.2)	4 (0.4)
肝機能異常	0	0	0	0	1 (0.1)	1 (0.1)
脂肪肝	0	0	0	0	1 (0.1)	3 (0.3)
高ビリルビン血症	0	0	0	1 (0.1)	0	0
臨床検査	0	1 (0.8)	2 (1.6)	11 (1.1)	14 (1.4)	13 (1.3)
アラニンアミノトランスフェラーゼ異常	0	0	0	0	0	1 (0.1)
アラニンアミノトランスフェラーゼ増加	0	1 (0.8)	2 (1.6)	10 (1.0)	7 (0.7)	9 (0.9)
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (0.8)	1 (0.8)	6 (0.6)	6 (0.6)	7 (0.7)
血中ビリルビン増加	0	0	0	0	3 (0.3)	0
肝酵素上昇	0	0	0	0	1 (0.1)	0
トランスアミナーゼ上昇	0	0	0	0	0	1 (0.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or up to 30 days after the last dose of study drug in DB Period, whichever occurs first.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total.
A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
Subjects are counted once in each row, regardless of the number of events they may have had.

相互参照：ISS Table 2.4　1.3.17.9

表 2.7.4.7-76. プラセボ対照併合解析集団（16 週，M16-045 試験，M16-047 試験，M17-377 試験，M16-048 試験及び M18-891 試験）の青少年被験者及び成人被験者の薬剤に関連する肝障害の発現割合（全体集団及び日本人集団）

Subgroup: Adolescent

MedDRA 22.1 System Organ Class Preferred Term	Japan Placebo (N=10) n (%)	Japan Active UPA 15 mg QD (N=11) n (%)	Japan Active UPA 30 mg QD (N=12) n (%)	Overall Placebo (N=124) n (%)	Overall Active UPA 15 mg QD (N=124) n (%)	Overall Active UPA 30 mg QD (N=124) n (%)
Any adverse event	0	0	0	0	5 (4.0)	0
肝胆道系障害	0	0	0	0	1 (0.8)	0
肝機能異常	0	0	0	0	1 (0.8)	0
臨床検査	0	0	0	0	4 (3.2)	0
アラニンアミノトランスフェラーゼ増加	0	0	0	0	1 (0.8)	0
アスパラギン酸アミノトランスフェラーゼ増加	0	0	0	0	2 (1.6)	0
血中ビリルビン増加	0	0	0	0	1 (0.8)	0
肝酵素上昇	0	0	0	0	1 (0.8)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or up to 30 days after the last dose of study drug in DB Period, whichever occurs first.
Subjects are counted once in each row, regardless of the number of events they may have had.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total.
A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

Subgroup: Adult

MedDRA 22.1 System Organ Class Preferred Term	Japan Placebo (N=114) n (%)	Japan Active UPA 15 mg QD (N=114) n (%)	Japan Active UPA 30 mg QD (N=115) n (%)	Overall Placebo (N=868) n (%)	Overall Active UPA 15 mg QD (N=866) n (%)	Overall Active UPA 30 mg QD (N=873) n (%)
Any adverse event	0	1 (0.9)	2 (1.7)	12 (1.4)	11 (1.3)	16 (1.8)
肝胆道系障害	0	0	0	1 (0.1)	1 (0.1)	4 (0.5)
肝機能異常	0	0	0	0	0	1 (0.1)
脂肪肝	0	0	0	0	1 (0.1)	3 (0.3)
高ビリルビン血症	0	0	0	1 (0.1)	0	0
臨床検査	0	1 (0.9)	2 (1.7)	11 (1.3)	10 (1.2)	13 (1.5)
アラニンアミノトランスフェラーゼ異常	0	0	0	0	0	1 (0.1)
アラニンアミノトランスフェラーゼ増加	0	1 (0.9)	2 (1.7)	10 (1.2)	6 (0.7)	9 (1.0)
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (0.9)	1 (0.9)	6 (0.7)	4 (0.5)	7 (0.8)
血中ビリルビン増加	0	0	0	0	2 (0.2)	0
トランスアミナーゼ上昇	0	0	0	0	0	1 (0.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or up to 30 days after the last dose of study drug in DB Period, whichever occurs first.
Subjects are counted once in each row, regardless of the number of events they may have had.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total.
A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

相互参照：ISS Table 2.4　1.6.7.9

表 2.7.4.7-77. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の 100 人年あたりの薬剤に関連する肝障害の発現率（全体集団及び日本人集団）

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=135.8) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=137.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1371) (PYS=955.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1378) (PYS=974.2) Events (E/100PY)
Any adverse event	9 (6.6)	8 (5.8)	59 (6.2)	72 (7.4)
肝胆道系障害	1 (0.7)	0	5 (0.5)	16 (1.6)
肝機能異常	1 (0.7)	0	4 (0.4)	1 (0.1)
脂肪肝	0	0	1 (0.1)	9 (0.9)
肝細胞損傷	0	0	0	1 (0.1)
肝腫大	0	0	0	3 (0.3)
高ビリルビン血症	0	0	0	1 (0.1)
非アルコール性脂肪性肝炎	0	0	0	1 (0.1)
臨床検査	8 (5.9)	8 (5.8)	54 (5.7)	56 (5.7)
アラニンアミノトランスフェラーゼ異常	0	0	0	1 (0.1)
アラニンアミノトランスフェラーゼ増加	5 (3.7)	5 (3.6)	29 (3.0)	27 (2.8)
アスパラギン酸アミノトランスフェラーゼ異常	0	0	1 (0.1)	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)	2 (1.5)	16 (1.7)	19 (2.0)
血中ビリルビン増加	0	0	3 (0.3)	0
肝酵素上昇	1 (0.7)	0	3 (0.3)	2 (0.2)
肝機能検査値上昇	0	0	1 (0.1)	0
トランスアミナーゼ上昇	0	1 (0.7)	1 (0.1)	7 (0.7)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：ISS Table 2.4　2.4.1.9

表 2.7.4.7-78. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の青少年被験者及び成人被験者の 100 人年あたりの薬剤に関連する肝障害の発現率（全体集団及び日本人集団）

Subgroup: Adolescent

	Japan		Overall	
MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=16) (PYS=11.7) Events (E/100PY)	UPA 30 mg QD (N=16) (PYS=11.3) Events (E/100PY)	UPA 15 mg QD (N=181) (PYS=132.5) Events (E/100PY)	UPA 30 mg QD (N=180) (PYS=134.1) Events (E/100PY)
Any adverse event	0	0	9 (6.8)	2 (1.5)
肝胆道系障害	0	0	1 (0.8)	1 (0.7)
肝機能異常	0	0	1 (0.8)	0
高ビリルビン血症	0	0	0	1 (0.7)
臨床検査	0	0	8 (6.0)	1 (0.7)
アラニンアミノトランスフェラーゼ増加	0	0	1 (0.8)	0
アスパラギン酸アミノトランスフェラーゼ増加	0	0	4 (3.0)	0
血中ビリルビン増加	0	0	1 (0.8)	0
肝酵素上昇	0	0	1 (0.8)	1 (0.7)
トランスアミナーゼ上昇	0	0	1 (0.8)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

Subgroup: Adult

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=161) (PYS=124.1) Events (E/100PY)	Japan UPA 30 mg QD (N=165) (PYS=126.0) Events (E/100PY)	Overall UPA 15 mg QD (N=1190) (PYS=822.4) Events (E/100PY)	Overall UPA 30 mg QD (N=1198) (PYS=840.1) Events (E/100PY)
Any adverse event	9 (7.2)	8 (6.3)	50 (6.1)	70 (8.3)
肝胆道系障害	1 (0.8)	0	4 (0.5)	15 (1.8)
肝機能異常	1 (0.8)	0	3 (0.4)	1 (0.1)
脂肪肝	0	0	1 (0.1)	9 (1.1)
肝細胞損傷	0	0	0	1 (0.1)
肝腫大	0	0	0	3 (0.4)
非アルコール性脂肪性肝炎	0	0	0	1 (0.1)
臨床検査	8 (6.4)	8 (6.3)	46 (5.6)	55 (6.5)
アラニンアミノトランスフェラーゼ異常	0	0	0	1 (0.1)
アラニンアミノトランスフェラーゼ増加	5 (4.0)	5 (4.0)	28 (3.4)	27 (3.2)
アスパラギン酸アミノトランスフェラーゼ異常	0	0	1 (0.1)	0
アスパラギン酸アミノトランスフェラーゼ増加	2 (1.6)	2 (1.6)	12 (1.5)	19 (2.3)
血中ビリルビン増加	0	0	2 (0.2)	0
肝酵素上昇	1 (0.8)	0	2 (0.2)	1 (0.1)
肝機能検査値上昇	0	0	1 (0.1)	0
トランスアミナーゼ上昇	0	1 (0.8)	0	7 (0.8)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：ISS Table 2.4　2.9.5.9

表 2.7.4.7-79. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の 100 人年あたりの薬剤に関連する肝障害の発現率（全体集団及び日本人集団，更新時）

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=225.5) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=228.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1372) (PYS=1407.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1380) (PYS=1446.5) Events (E/100PY)
Any adverse event	13 (5.8)	19 (8.3)	86 (6.1)	110 (7.6)
肝胆道系障害	3 (1.3)	3 (1.3)	17 (1.2)	26 (1.8)
肝機能異常	0	2 (0.9)	7 (0.5)	7 (0.5)
脂肪肝	3 (1.3)	1 (0.4)	8 (0.6)	12 (0.8)
肝炎	0	0	0	1 (<0.1)
肝細胞損傷	0	0	0	1 (<0.1)
肝腫大	0	0	0	3 (0.2)
高ビリルビン血症	0	0	2 (0.1)	1 (<0.1)
非アルコール性脂肪性肝炎	0	0	0	1 (<0.1)
臨床検査	10 (4.4)	16 (7.0)	69 (4.9)	84 (5.8)
アラニンアミノトランスフェラーゼ異常	0	0	0	1 (<0.1)
アラニンアミノトランスフェラーゼ増加	6 (2.7)	8 (3.5)	36 (2.6)	37 (2.6)
アスパラギン酸アミノトランスフェラーゼ異常	0	0	1 (<0.1)	0
アスパラギン酸アミノトランスフェラーゼ増加	3 (1.3)	4 (1.8)	21 (1.5)	29 (2.0)
血中ビリルビン増加	0	0	3 (0.2)	3 (0.2)
γ－グルタミルトランスフェラーゼ増加	0	2 (0.9)	0	2 (0.1)
肝酵素上昇	1 (0.4)	0	3 (0.2)	2 (0.1)
肝機能検査異常	0	0	1 (<0.1)	1 (<0.1)
肝機能検査値上昇	0	0	1 (<0.1)	0
トランスアミナーゼ上昇	0	2 (0.9)	3 (0.2)	9 (0.6)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：Updated ISS Table 2.4　2.4.1.9

表 2.7.4.7-80. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の青少年被験者及び成人被験者の 100 人年あたりの薬剤に関連する肝障害の発現率（全体集団及び日本人集団，更新時）

	Japan		Overall	
MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=16) (PYS=19.9) Events (E/100PY)	UPA 30 mg QD (N=16) (PYS=18.3) Events (E/100PY)	UPA 15 mg QD (N=181) (PYS=194.3) Events (E/100PY)	UPA 30 mg QD (N=180) (PYS=197.0) Events (E/100PY)
Subgroup: Adolescent				
Any adverse event	0	0	13 (6.7)	2 (1.0)
肝胆道系障害	0	0	2 (1.0)	1 (0.5)
肝機能異常	0	0	2 (1.0)	0
高ビリルビン血症	0	0	0	1 (0.5)
臨床検査	0	0	11 (5.7)	1 (0.5)
アラニンアミノトランスフェラーゼ増加	0	0	3 (1.5)	0
アスパラギン酸アミノトランスフェラーゼ増加	0	0	5 (2.6)	0
血中ビリルビン増加	0	0	1 (0.5)	0
肝酵素上昇	0	0	1 (0.5)	1 (0.5)
トランスアミナーゼ上昇	0	0	1 (0.5)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=161) (PYS=205.6) Events (E/100PY)	Japan UPA 30 mg QD (N=165) (PYS=210.0) Events (E/100PY)	Overall UPA 15 mg QD (N=1191) (PYS=1212.7) Events (E/100PY)	Overall UPA 30 mg QD (N=1200) (PYS=1249.5) Events (E/100PY)
Subgroup: Adult				
Any adverse event	13 (6.3)	19 (9.0)	73 (6.0)	108 (8.6)
肝胆道系障害	3 (1.5)	3 (1.4)	15 (1.2)	25 (2.0)
肝機能異常	0	2 (1.0)	5 (0.4)	7 (0.6)
脂肪肝	3 (1.5)	1 (0.5)	8 (0.7)	12 (1.0)
肝炎	0	0	0	1 (<0.1)
肝細胞損傷	0	0	0	1 (<0.1)
肝腫大	0	0	0	3 (0.2)
高ビリルビン血症	0	0	2 (0.2)	0
非アルコール性脂肪性肝炎	0	0	0	1 (<0.1)
臨床検査	10 (4.9)	16 (7.6)	58 (4.8)	83 (6.6)
アラニンアミノトランスフェラーゼ異常	0	0	0	1 (<0.1)
アラニンアミノトランスフェラーゼ増加	6 (2.9)	8 (3.8)	33 (2.7)	37 (3.0)
アスパラギン酸アミノトランスフェラーゼ異常	0	0	1 (<0.1)	0
アスパラギン酸アミノトランスフェラーゼ増加	3 (1.5)	4 (1.9)	16 (1.3)	29 (2.3)
血中ビリルビン増加	0	0	2 (0.2)	3 (0.2)
γーグルタミルトランスフェラーゼ増加	0	2 (1.0)	0	2 (0.2)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=161) (PYS=205.6) Events (E/100PY)	Japan UPA 30 mg QD (N=165) (PYS=210.0) Events (E/100PY)	Overall UPA 15 mg QD (N=1191) (PYS=1212.7) Events (E/100PY)	Overall UPA 30 mg QD (N=1200) (PYS=1249.5) Events (E/100PY)
Subgroup: Adult				
臨床検査 (Cont.)				
肝酵素上昇	1 (0.5)	0	2 (0.2)	1 (<0.1)
肝機能検査異常	0	0	1 (<0.1)	1 (<0.1)
肝機能検査値上昇	0	0	1 (<0.1)	0
トランスアミナーゼ上昇	0	2 (1.0)	2 (0.2)	9 (0.7)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：Updated ISS Table 2.4　2.9.5.9

表 2.7.4.7-81. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の 100 人年あたりの消化管穿孔の発現率（全体集団及び日本人集団，更新時）

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=225.5) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=228.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1372) (PYS=1407.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1380) (PYS=1446.5) Events (E/100PY)
Any adverse event	0	0	1 (<0.1)	0
胃腸障害	0	0	1 (<0.1)	0
腸管穿孔	0	0	1 (<0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：Updated ISS Table 2.4　2.4.1.10

表 2.7.4.7-82. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の青少年被験者及び成人被験者の 100 人年あたりの消化管穿孔の発現率（全体集団及び日本人集団，更新時）

	Japan		Overall	
MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=16) (PYS=19.9) Events (E/100PY)	UPA 30 mg QD (N=16) (PYS=18.3) Events (E/100PY)	UPA 15 mg QD (N=181) (PYS=194.3) Events (E/100PY)	UPA 30 mg QD (N=180) (PYS=197.0) Events (E/100PY)
Subgroup: Adolescent				
Any adverse event	0	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=161) (PYS=205.6) Events (E/100PY)	Japan UPA 30 mg QD (N=165) (PYS=210.0) Events (E/100PY)	Overall UPA 15 mg QD (N=1191) (PYS=1212.7) Events (E/100PY)	Overall UPA 30 mg QD (N=1200) (PYS=1249.5) Events (E/100PY)
Subgroup: Adult				
Any adverse event	0	0	1 (<0.1)	0
胃腸障害	0	0	1 (<0.1)	0
腸管穿孔	0	0	1 (<0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：Updated ISS Table 2.4　2.9.5.10

表 2.7.4.7-83. プラセボ対照併合解析集団（16 週，M16-045 試験，M16-047 試験，M17-377 試験，M16-048 試験及び M18-891 試験）の貧血の発現割合（全体集団及び日本人集団）

MedDRA 22.1 System Organ Class Preferred Term	Japan Placebo (N=124) n (%)	Japan Active UPA 15 mg QD (N=125) n (%)	Japan Active UPA 30 mg QD (N=127) n (%)	Overall Placebo (N=992) n (%)	Overall Active UPA 15 mg QD (N=990) n (%)	Overall Active UPA 30 mg QD (N=997) n (%)
Any adverse event	1 (0.8)	0	1 (0.8)	4 (0.4)	3 (0.3)	14 (1.4)
血液およびリンパ系障害	1 (0.8)	0	1 (0.8)	3 (0.3)	2 (0.2)	11 (1.1)
貧血	1 (0.8)	0	1 (0.8)	2 (0.2)	2 (0.2)	10 (1.0)
鉄欠乏性貧血	0	0	0	1 (0.1)	0	1 (0.1)
臨床検査	0	0	0	1 (0.1)	1 (0.1)	3 (0.3)
ヘモグロビン減少	0	0	0	1 (0.1)	1 (0.1)	3 (0.3)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or up to 30 days after the last dose of study drug in DB Period, whichever occurs first.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total.
A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
Subjects are counted once in each row, regardless of the number of events they may have had.

相互参照：ISS Table 2.4　1.3.17.11

表 2.7.4.7-84. プラセボ対照併合解析集団（16 週，M16-045 試験，M16-047 試験，M17-377 試験，M16-048 試験及び M18-891 試験）の青少年被験者及び成人被験者の貧血の発現割合（全体集団及び日本人集団）

Subgroup: Adolescent

MedDRA 22.1 System Organ Class Preferred Term	Japan Placebo (N=10) n (%)	Japan Active UPA 15 mg QD (N=11) n (%)	Japan Active UPA 30 mg QD (N=12) n (%)	Overall Placebo (N=124) n (%)	Overall Active UPA 15 mg QD (N=124) n (%)	Overall Active UPA 30 mg QD (N=124) n (%)
Any adverse event	0	0	0	0	1 (0.8)	0
臨床検査	0	0	0	0	1 (0.8)	0
ヘモグロビン減少	0	0	0	0	1 (0.8)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or up to 30 days after the last dose of study drug in DB Period, whichever occurs first.
Subjects are counted once in each row, regardless of the number of events they may have had.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total.
A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

Subgroup: Adult

MedDRA 22.1 System Organ Class Preferred Term	Japan Placebo (N=114) n (%)	Japan Active UPA 15 mg QD (N=114) n (%)	Japan Active UPA 30 mg QD (N=115) n (%)	Overall Placebo (N=868) n (%)	Overall Active UPA 15 mg QD (N=866) n (%)	Overall Active UPA 30 mg QD (N=873) n (%)
Any adverse event	1 (0.9)	0	1 (0.9)	4 (0.5)	2 (0.2)	14 (1.6)
血液およびリンパ系障害	1 (0.9)	0	1 (0.9)	3 (0.3)	2 (0.2)	11 (1.3)
貧血	1 (0.9)	0	1 (0.9)	2 (0.2)	2 (0.2)	10 (1.1)
鉄欠乏性貧血	0	0	0	1 (0.1)	0	1 (0.1)
臨床検査	0	0	0	1 (0.1)	0	3 (0.3)
ヘモグロビン減少	0	0	0	1 (0.1)	0	3 (0.3)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or up to 30 days after the last dose of study drug in DB Period, whichever occurs first.
Subjects are counted once in each row, regardless of the number of events they may have had.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total.
A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

相互参照：ISS Table 2.4　1.6.7.11

表 2.7.4.7-85. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の 100 人年あたりの貧血の発現率（全体集団及び日本人集団）

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=135.8) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=137.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1371) (PYS=955.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1378) (PYS=974.2) Events (E/100PY)
Any adverse event	4 (2.9)	5 (3.6)	12 (1.3)	33 (3.4)
血液およびリンパ系障害	2 (1.5)	4 (2.9)	5 (0.5)	27 (2.8)
貧血	2 (1.5)	4 (2.9)	5 (0.5)	22 (2.3)
ビタミンB12欠乏性貧血	0	0	0	2 (0.2)
欠乏性貧血	0	0	0	1 (0.1)
鉄欠乏性貧血	0	0	0	2 (0.2)
臨床検査	2 (1.5)	1 (0.7)	7 (0.7)	6 (0.6)
ヘモグロビン減少	2 (1.5)	1 (0.7)	6 (0.6)	6 (0.6)
平均赤血球容積増加	0	0	1 (0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：ISS Table 2.4　2.4.1.11

表 2.7.4.7-86. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の青少年被験者及び成人被験者の 100 人年あたりの貧血の発現率（全体集団及び日本人集団）

Subgroup: Adolescent

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=16) (PYS=11.7) Events (E/100PY)	Japan UPA 30 mg QD (N=16) (PYS=11.3) Events (E/100PY)	Overall UPA 15 mg QD (N=181) (PYS=132.5) Events (E/100PY)	Overall UPA 30 mg QD (N=180) (PYS=134.1) Events (E/100PY)
Any adverse event	0	0	4 (3.0)	1 (0.7)
血液およびリンパ系障害	0	0	0	1 (0.7)
貧血	0	0	0	1 (0.7)
臨床検査	0	0	4 (3.0)	0
ヘモグロビン減少	0	0	3 (2.3)	0
平均赤血球容積増加	0	0	1 (0.8)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

Subgroup: Adult

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=161) (PYS=124.1) Events (E/100PY)	Japan UPA 30 mg QD (N=165) (PYS=126.0) Events (E/100PY)	Overall UPA 15 mg QD (N=1190) (PYS=822.4) Events (E/100PY)	Overall UPA 30 mg QD (N=1198) (PYS=840.1) Events (E/100PY)
Any adverse event	4 (3.2)	5 (4.0)	8 (1.0)	32 (3.8)
血液およびリンパ系障害	2 (1.6)	4 (3.2)	5 (0.6)	26 (3.1)
貧血	2 (1.6)	4 (3.2)	5 (0.6)	21 (2.5)
ビタミンB12欠乏性貧血	0	0	0	2 (0.2)
欠乏性貧血	0	0	0	1 (0.1)
鉄欠乏性貧血	0	0	0	2 (0.2)
臨床検査	2 (1.6)	1 (0.8)	3 (0.4)	6 (0.7)
ヘモグロビン減少	2 (1.6)	1 (0.8)	3 (0.4)	6 (0.7)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：ISS Table 2.4　2.9.5.11

表 2.7.4.7-87. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の 100 人年あたりの貧血の発現率（全体集団及び日本人集団，更新時）

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=225.5) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=228.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1372) (PYS=1407.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1380) (PYS=1446.5) Events (E/100PY)
Any adverse event	6 (2.7)	7 (3.1)	19 (1.4)	49 (3.4)
血液およびリンパ系障害	4 (1.8)	4 (1.8)	11 (0.8)	35 (2.4)
貧血	4 (1.8)	4 (1.8)	10 (0.7)	28 (1.9)
大球性貧血	0	0	0	1 (<0.1)
ビタミンＢ１２欠乏性貧血	0	0	0	2 (0.1)
欠乏性貧血	0	0	1 (<0.1)	1 (<0.1)
鉄欠乏性貧血	0	0	0	3 (0.2)
臨床検査	2 (0.9)	3 (1.3)	8 (0.6)	14 (1.0)
ヘモグロビン減少	2 (0.9)	3 (1.3)	7 (0.5)	14 (1.0)
平均赤血球容積増加	0	0	1 (<0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：Updated ISS Table 2.4　2.4.1.11

表 2.7.4.7-88. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の青少年被験者及び成人被験者の 100 人年あたりの貧血の発現率（全体集団及び日本人集団，更新時）

	Japan		Overall	
MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=16) (PYS=19.9) Events (E/100PY)	UPA 30 mg QD (N=16) (PYS=18.3) Events (E/100PY)	UPA 15 mg QD (N=181) (PYS=194.3) Events (E/100PY)	UPA 30 mg QD (N=180) (PYS=197.0) Events (E/100PY)
Subgroup: Adolescent				
Any adverse event	2 (10.1)	0	9 (4.6)	2 (1.0)
血液およびリンパ系障害	2 (10.1)	0	5 (2.6)	1 (0.5)
貧血	2 (10.1)	0	5 (2.6)	1 (0.5)
臨床検査	0	0	4 (2.1)	1 (0.5)
ヘモグロビン減少	0	0	3 (1.5)	1 (0.5)
平均赤血球容積増加	0	0	1 (0.5)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=161) (PYS=205.6) Events (E/100PY)	Japan UPA 30 mg QD (N=165) (PYS=210.0) Events (E/100PY)	Overall UPA 15 mg QD (N=1191) (PYS=1212.7) Events (E/100PY)	Overall UPA 30 mg QD (N=1200) (PYS=1249.5) Events (E/100PY)
Subgroup: Adult				
Any adverse event	4 (1.9)	7 (3.3)	10 (0.8)	47 (3.8)
血液およびリンパ系障害	2 (1.0)	4 (1.9)	6 (0.5)	34 (2.7)
貧血	2 (1.0)	4 (1.9)	5 (0.4)	27 (2.2)
大球性貧血	0	0	0	1 (<0.1)
ビタミンＢ１２欠乏性貧血	0	0	0	2 (0.2)
欠乏性貧血	0	0	1 (<0.1)	1 (<0.1)
鉄欠乏性貧血	0	0	0	3 (0.2)
臨床検査	2 (1.0)	3 (1.4)	4 (0.3)	13 (1.0)
ヘモグロビン減少	2 (1.0)	3 (1.4)	4 (0.3)	13 (1.0)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：Updated ISS Table 2.4　2.9.5.11

表 2.7.4.7-89. プラセボ対照併合解析集団（16 週，M16-045 試験，M16-047 試験，M17-377 試験，M16-048 試験及び M18-891 試験）の好中球減少症の発現割合（全体集団及び日本人集団）

MedDRA 22.1 System Organ Class Preferred Term	Japan Placebo (N=124) n (%)	Japan Active UPA 15 mg QD (N=125) n (%)	Japan Active UPA 30 mg QD (N=127) n (%)	Overall Placebo (N=992) n (%)	Overall Active UPA 15 mg QD (N=990) n (%)	Overall Active UPA 30 mg QD (N=997) n (%)
Any adverse event	0	1 (0.8)	4 (3.1)	3 (0.3)	11 (1.1)	30 (3.0)
血液およびリンパ系障害	0	0	3 (2.4)	2 (0.2)	7 (0.7)	24 (2.4)
好中球減少症	0	0	3 (2.4)	2 (0.2)	7 (0.7)	24 (2.4)
臨床検査	0	1 (0.8)	1 (0.8)	1 (0.1)	4 (0.4)	6 (0.6)
好中球数減少	0	1 (0.8)	1 (0.8)	1 (0.1)	4 (0.4)	6 (0.6)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or up to 30 days after the last dose of study drug in DB Period, whichever occurs first.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total.
A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
Subjects are counted once in each row, regardless of the number of events they may have had.

相互参照：ISS Table 2.4　1.3.17.12

表 2.7.4.7-90. プラセボ対照併合解析集団（16 週，M16-045 試験，M16-047 試験，M17-377 試験，M16-048 試験及び M18-891 試験）の青少年被験者及び成人被験者の好中球減少症の発現割合（全体集団及び日本人集団）

Subgroup: Adolescent

MedDRA 22.1 System Organ Class Preferred Term	Japan Placebo (N=10) n (%)	Japan Active UPA 15 mg QD (N=11) n (%)	Japan Active UPA 30 mg QD (N=12) n (%)	Overall Placebo (N=124) n (%)	Overall Active UPA 15 mg QD (N=124) n (%)	Overall Active UPA 30 mg QD (N=124) n (%)
Any adverse event	0	0	0	1 (0.8)	2 (1.6)	6 (4.8)
血液およびリンパ系障害	0	0	0	1 (0.8)	1 (0.8)	5 (4.0)
好中球減少症	0	0	0	1 (0.8)	1 (0.8)	5 (4.0)
臨床検査	0	0	0	0	1 (0.8)	1 (0.8)
好中球数減少	0	0	0	0	1 (0.8)	1 (0.8)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or up to 30 days after the last dose of study drug in DB Period, whichever occurs first.
Subjects are counted once in each row, regardless of the number of events they may have had.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total.
A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

Subgroup: Adult

MedDRA 22.1 System Organ Class Preferred Term	Japan Placebo (N=114) n (%)	Japan Active UPA 15 mg QD (N=114) n (%)	Japan Active UPA 30 mg QD (N=115) n (%)	Overall Placebo (N=868) n (%)	Overall Active UPA 15 mg QD (N=866) n (%)	Overall Active UPA 30 mg QD (N=873) n (%)
Any adverse event	0	1 (0.9)	4 (3.5)	2 (0.2)	9 (1.0)	24 (2.7)
血液およびリンパ系障害	0	0	3 (2.6)	1 (0.1)	6 (0.7)	19 (2.2)
好中球減少症	0	0	3 (2.6)	1 (0.1)	6 (0.7)	19 (2.2)
臨床検査	0	1 (0.9)	1 (0.9)	1 (0.1)	3 (0.3)	5 (0.6)
好中球数減少	0	1 (0.9)	1 (0.9)	1 (0.1)	3 (0.3)	5 (0.6)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or up to 30 days after the last dose of study drug in DB Period, whichever occurs first.
Subjects are counted once in each row, regardless of the number of events they may have had.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total.
A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

相互参照：ISS Table 2.4　1.6.7.12

表 2.7.4.7-91. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の 100 人年あたりの好中球減少症の発現率（全体集団及び日本人集団）

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=135.8) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=137.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1371) (PYS=955.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1378) (PYS=974.2) Events (E/100PY)
Any adverse event	1 (0.7)	6 (4.4)	23 (2.4)	48 (4.9)
血液およびリンパ系障害	0	4 (2.9)	11 (1.2)	36 (3.7)
好中球減少症	0	4 (2.9)	11 (1.2)	36 (3.7)
臨床検査	1 (0.7)	2 (1.5)	12 (1.3)	12 (1.2)
好中球数減少	1 (0.7)	2 (1.5)	11 (1.2)	12 (1.2)
好中球百分率減少	0	0	1 (0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：ISS Table 2.4　2.4.1.12

表 2.7.4.7-92. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の青少年被験者及び成人被験者の 100 人年あたりの好中球減少症の発現率（全体集団及び日本人集団）

Subgroup: Adolescent

	Japan		Overall	
MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=16) (PYS=11.7) Events (E/100PY)	UPA 30 mg QD (N=16) (PYS=11.3) Events (E/100PY)	UPA 15 mg QD (N=181) (PYS=132.5) Events (E/100PY)	UPA 30 mg QD (N=180) (PYS=134.1) Events (E/100PY)
Any adverse event	0	0	4 (3.0)	12 (8.9)
血液およびリンパ系障害	0	0	1 (0.8)	8 (6.0)
好中球減少症	0	0	1 (0.8)	8 (6.0)
臨床検査	0	0	3 (2.3)	4 (3.0)
好中球数減少	0	0	2 (1.5)	4 (3.0)
好中球百分率減少	0	0	1 (0.8)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

Subgroup: Adult

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=161) (PYS=124.1) Events (E/100PY)	Japan UPA 30 mg QD (N=165) (PYS=126.0) Events (E/100PY)	Overall UPA 15 mg QD (N=1190) (PYS=822.4) Events (E/100PY)	Overall UPA 30 mg QD (N=1198) (PYS=840.1) Events (E/100PY)
Any adverse event	1 (0.8)	6 (4.8)	19 (2.3)	36 (4.3)
血液およびリンパ系障害	0	4 (3.2)	10 (1.2)	28 (3.3)
好中球減少症	0	4 (3.2)	10 (1.2)	28 (3.3)
臨床検査	1 (0.8)	2 (1.6)	9 (1.1)	8 (1.0)
好中球数減少	1 (0.8)	2 (1.6)	9 (1.1)	8 (1.0)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：ISS Table 2.4　2.9.5.12

表 2.7.4.7-93. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の 100 人年あたりの好中球減少症の発現率（全体集団及び日本人集団，更新時）

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=225.5) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=228.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1372) (PYS=1407.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1380) (PYS=1446.5) Events (E/100PY)
Any adverse event	2 (0.9)	8 (3.5)	27 (1.9)	58 (4.0)
血液およびリンパ系障害	0	6 (2.6)	12 (0.9)	43 (3.0)
好中球減少症	0	6 (2.6)	12 (0.9)	43 (3.0)
臨床検査	2 (0.9)	2 (0.9)	15 (1.1)	15 (1.0)
好中球数減少	2 (0.9)	2 (0.9)	14 (1.0)	15 (1.0)
好中球百分率減少	0	0	1 (<0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：Updated ISS Table 2.4　2.4.1.12

表 2.7.4.7-94. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の青少年被験者及び成人被験者の 100 人年あたりの好中球減少症の発現率（全体集団及び日本人集団，更新時）

	---------- Japan ----------		---------- Overall ----------	
MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=16) (PYS=19.9) Events (E/100PY)	UPA 30 mg QD (N=16) (PYS=18.3) Events (E/100PY)	UPA 15 mg QD (N=181) (PYS=194.3) Events (E/100PY)	UPA 30 mg QD (N=180) (PYS=197.0) Events (E/100PY)
Subgroup: Adolescent				
Any adverse event	0	0	6 (3.1)	15 (7.6)
血液およびリンパ系障害	0	0	2 (1.0)	10 (5.1)
好中球減少症	0	0	2 (1.0)	10 (5.1)
臨床検査	0	0	4 (2.1)	5 (2.5)
好中球数減少	0	0	3 (1.5)	5 (2.5)
好中球百分率減少	0	0	1 (0.5)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=161) (PYS=205.6) Events (E/100PY)	Japan UPA 30 mg QD (N=165) (PYS=210.0) Events (E/100PY)	Overall UPA 15 mg QD (N=1191) (PYS=1212.7) Events (E/100PY)	Overall UPA 30 mg QD (N=1200) (PYS=1249.5) Events (E/100PY)
Subgroup: Adult				
Any adverse event	2 (1.0)	8 (3.8)	21 (1.7)	43 (3.4)
血液およびリンパ系障害	0	6 (2.9)	10 (0.8)	33 (2.6)
好中球減少症	0	6 (2.9)	10 (0.8)	33 (2.6)
臨床検査	2 (1.0)	2 (1.0)	11 (0.9)	10 (0.8)
好中球数減少	2 (1.0)	2 (1.0)	11 (0.9)	10 (0.8)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：Updated ISS Table 2.4　2.9.5.12

表 2.7.4.7-95. プラセボ対照併合解析集団（16 週，M16-045 試験，M16-047 試験，M17-377 試験，M16-048 試験及び M18-891 試験）のリンパ球減少症の発現割合（全体集団及び日本人集団）

MedDRA 22.1 System Organ Class Preferred Term	Japan Placebo (N=124) n (%)	Japan Active UPA 15 mg QD (N=125) n (%)	Japan Active UPA 30 mg QD (N=127) n (%)	Overall Placebo (N=992) n (%)	Overall Active UPA 15 mg QD (N=990) n (%)	Overall Active UPA 30 mg QD (N=997) n (%)
Any adverse event	0	0	0	3 (0.3)	2 (0.2)	3 (0.3)
血液およびリンパ系障害	0	0	0	1 (0.1)	2 (0.2)	2 (0.2)
リンパ球減少症	0	0	0	1 (0.1)	2 (0.2)	2 (0.2)
臨床検査	0	0	0	2 (0.2)	1 (0.1)	1 (0.1)
CD4リンパ球減少	0	0	0	0	1 (0.1)	0
CD8リンパ球減少	0	0	0	1 (0.1)	0	1 (0.1)
リンパ球数減少	0	0	0	1 (0.1)	0	0
Tリンパ球数減少	0	0	0	1 (0.1)	1 (0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or up to 30 days after the last dose of study drug in DB Period, whichever occurs first.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total.
A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
Subjects are counted once in each row, regardless of the number of events they may have had.

相互参照：ISS Table 2.4　1.3.17.13

表 2.7.4.7-96. プラセボ対照併合解析集団（16 週，M16-045 試験，M16-047 試験，M17-377 試験，M16-048 試験及び M18-891 試験）の青少年被験者及び成人被験者のリンパ球減少症の発現割合（全体集団及び日本人集団）

Subgroup: Adolescent

	Japan			Overall		
		Active			Active	
MedDRA 22.1 System Organ Class Preferred Term	Placebo (N=10) n (%)	UPA 15 mg QD (N=11) n (%)	UPA 30 mg QD (N=12) n (%)	Placebo (N=124) n (%)	UPA 15 mg QD (N=124) n (%)	UPA 30 mg QD (N=124) n (%)
Any adverse event	0	0	0	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or up to 30 days after the last dose of study drug in DB Period, whichever occurs first.
Subjects are counted once in each row, regardless of the number of events they may have had.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total.
A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

Subgroup: Adult

MedDRA 22.1 System Organ Class Preferred Term	Japan Placebo (N=114) n (%)	Japan Active UPA 15 mg QD (N=114) n (%)	Japan Active UPA 30 mg QD (N=115) n (%)	Overall Placebo (N=868) n (%)	Overall Active UPA 15 mg QD (N=866) n (%)	Overall Active UPA 30 mg QD (N=873) n (%)
Any adverse event	0	0	0	3 (0.3)	2 (0.2)	3 (0.3)
血液およびリンパ系障害	0	0	0	1 (0.1)	2 (0.2)	2 (0.2)
リンパ球減少症	0	0	0	1 (0.1)	2 (0.2)	2 (0.2)
臨床検査	0	0	0	2 (0.2)	1 (0.1)	1 (0.1)
CD4リンパ球減少	0	0	0	0	1 (0.1)	0
CD8リンパ球減少	0	0	0	1 (0.1)	0	1 (0.1)
リンパ球数減少	0	0	0	1 (0.1)	0	0
Tリンパ球数減少	0	0	0	1 (0.1)	1 (0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or up to 30 days after the last dose of study drug in DB Period, whichever occurs first.
Subjects are counted once in each row, regardless of the number of events they may have had.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total.
A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

相互参照：ISS Table 2.4　1.6.7.13

表 2.7.4.7-97. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の 100 人年あたりのリンパ球減少症の発現率（全体集団及び日本人集団）

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=135.8) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=137.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1371) (PYS=955.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1378) (PYS=974.2) Events (E/100PY)
Any adverse event	0	0	5 (0.5)	6 (0.6)
血液およびリンパ系障害	0	0	3 (0.3)	3 (0.3)
リンパ球減少症	0	0	3 (0.3)	3 (0.3)
臨床検査	0	0	2 (0.2)	3 (0.3)
CD4リンパ球減少	0	0	1 (0.1)	0
CD8リンパ球減少	0	0	0	1 (0.1)
リンパ球数減少	0	0	0	2 (0.2)
Tリンパ球数減少	0	0	1 (0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：ISS Table 2.4　2.4.1.13

表 2.7.4.7-98. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の青少年被験者及び成人被験者の 100 人年あたりのリンパ球減少症の発現率（全体集団及び日本人集団）

Subgroup: Adolescent

	Japan		Overall	
MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=16) (PYS=11.7) Events (E/100PY)	UPA 30 mg QD (N=16) (PYS=11.3) Events (E/100PY)	UPA 15 mg QD (N=181) (PYS=132.5) Events (E/100PY)	UPA 30 mg QD (N=180) (PYS=134.1) Events (E/100PY)
Any adverse event	0	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

Subgroup: Adult

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=161) (PYS=124.1) Events (E/100PY)	Japan UPA 30 mg QD (N=165) (PYS=126.0) Events (E/100PY)	Overall UPA 15 mg QD (N=1190) (PYS=822.4) Events (E/100PY)	Overall UPA 30 mg QD (N=1198) (PYS=840.1) Events (E/100PY)
Any adverse event	0	0	5 (0.6)	6 (0.7)
血液およびリンパ系障害	0	0	3 (0.4)	3 (0.4)
リンパ球減少症	0	0	3 (0.4)	3 (0.4)
臨床検査	0	0	2 (0.2)	3 (0.4)
CD4リンパ球減少	0	0	1 (0.1)	0
CD8リンパ球減少	0	0	0	1 (0.1)
リンパ球数減少	0	0	0	2 (0.2)
Tリンパ球数減少	0	0	1 (0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：ISS Table 2.4　2.9.5.13

表 2.7.4.7-99. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の 100 人年あたりのリンパ球減少症の発現率（全体集団及び日本人集団，更新時）

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=225.5) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=228.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1372) (PYS=1407.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1380) (PYS=1446.5) Events (E/100PY)
Any adverse event	0	1 (0.4)	7 (0.5)	11 (0.8)
血液およびリンパ系障害	0	1 (0.4)	4 (0.3)	6 (0.4)
リンパ球減少症	0	1 (0.4)	4 (0.3)	6 (0.4)
臨床検査	0	0	3 (0.2)	5 (0.3)
ＣＤ４リンパ球減少	0	0	1 (<0.1)	0
ＣＤ８リンパ球減少	0	0	0	1 (<0.1)
リンパ球数減少	0	0	1 (<0.1)	4 (0.3)
Ｔリンパ球数減少	0	0	1 (<0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：Updated ISS Table 2.4　2.4.1.13

表 2.7.4.7-100. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の青少年被験者及び成人被験者の 100 人年あたりのリンパ球減少症の発現率（全体集団及び日本人集団，更新時）

	---------- Japan ----------		---------- Overall ----------	
MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=16) (PYS=19.9) Events (E/100PY)	UPA 30 mg QD (N=16) (PYS=18.3) Events (E/100PY)	UPA 15 mg QD (N=181) (PYS=194.3) Events (E/100PY)	UPA 30 mg QD (N=180) (PYS=197.0) Events (E/100PY)
Subgroup: Adolescent				
Any adverse event	0	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=161) (PYS=205.6) Events (E/100PY)	Japan UPA 30 mg QD (N=165) (PYS=210.0) Events (E/100PY)	Overall UPA 15 mg QD (N=1191) (PYS=1212.7) Events (E/100PY)	Overall UPA 30 mg QD (N=1200) (PYS=1249.5) Events (E/100PY)
Subgroup: Adult				
Any adverse event	0	1 (0.5)	7 (0.6)	11 (0.9)
血液およびリンパ系障害	0	1 (0.5)	4 (0.3)	6 (0.5)
リンパ球減少症	0	1 (0.5)	4 (0.3)	6 (0.5)
臨床検査	0	0	3 (0.2)	5 (0.4)
ＣＤ４リンパ球減少	0	0	1 (<0.1)	0
ＣＤ８リンパ球減少	0	0	0	1 (<0.1)
リンパ球数減少	0	0	1 (<0.1)	4 (0.3)
Ｔリンパ球数減少	0	0	1 (<0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：Updated ISS Table 2.4　2.9.5.13

表 2.7.4.7-101. プラセボ対照併合解析集団（16 週，M16-045 試験，M16-047 試験，M17-377 試験，M16-048 試験及び M18-891 試験）のクレアチンホスホキナーゼ増加の発現割合（全体集団及び日本人集団）

	Japan			Overall		
		Active			Active	
MedDRA 22.1 System Organ Class Preferred Term	Placebo (N=124) n (%)	UPA 15 mg QD (N=125) n (%)	UPA 30 mg QD (N=127) n (%)	Placebo (N=992) n (%)	UPA 15 mg QD (N=990) n (%)	UPA 30 mg QD (N=997) n (%)
Any adverse event	1 (0.8)	1 (0.8)	2 (1.6)	21 (2.1)	42 (4.2)	52 (5.2)
臨床検査	1 (0.8)	1 (0.8)	2 (1.6)	21 (2.1)	42 (4.2)	52 (5.2)
血中クレアチンホスホキナーゼ増加	1 (0.8)	1 (0.8)	2 (1.6)	21 (2.1)	42 (4.2)	52 (5.2)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or up to 30 days after the last dose of study drug in DB Period, whichever occurs first.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total.
A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
Subjects are counted once in each row, regardless of the number of events they may have had.

相互参照：ISS Table 2.4　1.3.17.15

表 2.7.4.7-102. プラセボ対照併合解析集団（16 週，M16-045 試験，M16-047 試験，M17-377 試験，M16-048 試験及び M18-891 試験）の青少年被験者及び成人被験者のクレアチンホスホキナーゼ増加の発現割合（全体集団及び日本人集団）

Subgroup: Adolescent

MedDRA 22.1 System Organ Class Preferred Term	Japan Placebo (N=10) n (%)	Japan Active UPA 15 mg QD (N=11) n (%)	Japan Active UPA 30 mg QD (N=12) n (%)	Overall Placebo (N=124) n (%)	Overall Active UPA 15 mg QD (N=124) n (%)	Overall Active UPA 30 mg QD (N=124) n (%)
Any adverse event	0	1 (9.1)	0	3 (2.4)	7 (5.6)	9 (7.3)
臨床検査	0	1 (9.1)	0	3 (2.4)	7 (5.6)	9 (7.3)
血中クレアチンホスホキナーゼ増加	0	1 (9.1)	0	3 (2.4)	7 (5.6)	9 (7.3)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or up to 30 days after the last dose of study drug in DB Period, whichever occurs first.
Subjects are counted once in each row, regardless of the number of events they may have had.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total.
A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

Subgroup: Adult

MedDRA 22.1 System Organ Class Preferred Term	Japan Placebo (N=114) n (%)	Japan Active UPA 15 mg QD (N=114) n (%)	Japan Active UPA 30 mg QD (N=115) n (%)	Overall Placebo (N=868) n (%)	Overall Active UPA 15 mg QD (N=866) n (%)	Overall Active UPA 30 mg QD (N=873) n (%)
Any adverse event	1 (0.9)	0	2 (1.7)	18 (2.1)	35 (4.0)	43 (4.9)
臨床検査	1 (0.9)	0	2 (1.7)	18 (2.1)	35 (4.0)	43 (4.9)
血中クレアチンホスホキナーゼ増加	1 (0.9)	0	2 (1.7)	18 (2.1)	35 (4.0)	43 (4.9)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or up to 30 days after the last dose of study drug in DB Period, whichever occurs first.
Subjects are counted once in each row, regardless of the number of events they may have had.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total.
A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

相互参照：ISS Table 2.4　1.6.7.15

表 2.7.4.7-103. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の 100 人年あたりのクレアチンホスホキナーゼ増加の発現率（全体集団及び日本人集団）

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=135.8) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=137.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1371) (PYS=955.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1378) (PYS=974.2) Events (E/100PY)
Any adverse event	2 (1.5)	6 (4.4)	84 (8.8)	105 (10.8)
臨床検査	2 (1.5)	6 (4.4)	84 (8.8)	105 (10.8)
血中クレアチンホスホキナーゼ増加	2 (1.5)	6 (4.4)	84 (8.8)	105 (10.8)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：ISS Table 2.4　2.4.1.15

表 2.7.4.7-104. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の青少年被験者及び成人被験者の 100 人年あたりのクレアチンホスホキナーゼ増加の発現率（全体集団及び日本人集団）

Subgroup: Adolescent

	Japan		Overall	
MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=16) (PYS=11.7) Events (E/100PY)	UPA 30 mg QD (N=16) (PYS=11.3) Events (E/100PY)	UPA 15 mg QD (N=181) (PYS=132.5) Events (E/100PY)	UPA 30 mg QD (N=180) (PYS=134.1) Events (E/100PY)
Any adverse event	1 (8.6)	1 (8.9)	19 (14.3)	15 (11.2)
臨床検査	1 (8.6)	1 (8.9)	19 (14.3)	15 (11.2)
血中クレアチンホスホキナーゼ増加	1 (8.6)	1 (8.9)	19 (14.3)	15 (11.2)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

Subgroup: Adult

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=161) (PYS=124.1) Events (E/100PY)	Japan UPA 30 mg QD (N=165) (PYS=126.0) Events (E/100PY)	Overall UPA 15 mg QD (N=1190) (PYS=822.4) Events (E/100PY)	Overall UPA 30 mg QD (N=1198) (PYS=840.1) Events (E/100PY)
Any adverse event	1 (0.8)	5 (4.0)	65 (7.9)	90 (10.7)
臨床検査	1 (0.8)	5 (4.0)	65 (7.9)	90 (10.7)
血中クレアチンホスホキナーゼ増加	1 (0.8)	5 (4.0)	65 (7.9)	90 (10.7)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：ISS Table 2.4　2.9.5.15

表 2.7.4.7-105. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の 100 人年あたりのクレアチンホスホキナーゼ増加の発現率（全体集団及び日本人集団，更新時）

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=225.5) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=228.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1372) (PYS=1407.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1380) (PYS=1446.5) Events (E/100PY)
Any adverse event	3 (1.3)	10 (4.4)	104 (7.4)	145 (10.0)
臨床検査	3 (1.3)	10 (4.4)	104 (7.4)	145 (10.0)
血中クレアチンホスホキナーゼ増加	3 (1.3)	10 (4.4)	104 (7.4)	145 (10.0)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：Updated ISS Table 2.4　2.4.1.15

表 2.7.4.7-106. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の青少年被験者及び成人被験者の 100 人年あたりのクレアチンホスホキナーゼ増加の発現率（全体集団及び日本人集団，更新時）

	Japan		Overall	
MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=16) (PYS=19.9) Events (E/100PY)	UPA 30 mg QD (N=16) (PYS=18.3) Events (E/100PY)	UPA 15 mg QD (N=181) (PYS=194.3) Events (E/100PY)	UPA 30 mg QD (N=180) (PYS=197.0) Events (E/100PY)
Subgroup: Adolescent				
Any adverse event	2 (10.1)	1 (5.5)	22 (11.3)	20 (10.2)
臨床検査	2 (10.1)	1 (5.5)	22 (11.3)	20 (10.2)
血中クレアチンホスホキナーゼ増加	2 (10.1)	1 (5.5)	22 (11.3)	20 (10.2)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=161) (PYS=205.6) Events (E/100PY)	Japan UPA 30 mg QD (N=165) (PYS=210.0) Events (E/100PY)	Overall UPA 15 mg QD (N=1191) (PYS=1212.7) Events (E/100PY)	Overall UPA 30 mg QD (N=1200) (PYS=1249.5) Events (E/100PY)
Subgroup: Adult				
Any adverse event	1 (0.5)	9 (4.3)	82 (6.8)	125 (10.0)
臨床検査	1 (0.5)	9 (4.3)	82 (6.8)	125 (10.0)
血中クレアチンホスホキナーゼ増加	1 (0.5)	9 (4.3)	82 (6.8)	125 (10.0)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：Updated ISS Table 2.4　2.9.5.15

表 2.7.4.7-107. プラセボ対照併合解析集団（16 週，M16-045 試験，M16-047 試験，M17-377 試験，M16-048 試験及び M18-891 試験）の腎機能障害の発現割合（全体集団及び日本人集団）

	Japan			Overall		
		Active			Active	
MedDRA 22.1 System Organ Class Preferred Term	Placebo (N=124) n (%)	UPA 15 mg QD (N=125) n (%)	UPA 30 mg QD (N=127) n (%)	Placebo (N=992) n (%)	UPA 15 mg QD (N=990) n (%)	UPA 30 mg QD (N=997) n (%)
Any adverse event	0	0	0	0	1 (0.1)	0
腎および尿路障害	0	0	0	0	1 (0.1)	0
急性腎障害	0	0	0	0	1 (0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or up to 30 days after the last dose of study drug in DB Period, whichever occurs first.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total.
A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.
Subjects are counted once in each row, regardless of the number of events they may have had.

相互参照：ISS Table 2.4 1.3.17.16

表 2.7.4.7-108. プラセボ対照併合解析集団（16 週，M16-045 試験，M16-047 試験，M17-377 試験，M16-048 試験及び M18-891 試験）の青少年被験者及び成人被験者の腎機能障害の発現割合（全体集団及び日本人集団）

Subgroup: Adolescent

MedDRA 22.1 System Organ Class Preferred Term	Japan Placebo (N=10) n (%)	Japan Active UPA 15 mg QD (N=11) n (%)	Japan Active UPA 30 mg QD (N=12) n (%)	Overall Placebo (N=124) n (%)	Overall Active UPA 15 mg QD (N=124) n (%)	Overall Active UPA 30 mg QD (N=124) n (%)
Any adverse event	0	0	0	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or up to 30 days after the last dose of study drug in DB Period, whichever occurs first.
Subjects are counted once in each row, regardless of the number of events they may have had.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total.
A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

Subgroup: Adult

MedDRA 22.1 System Organ Class Preferred Term	Japan Placebo (N=114) n (%)	Japan Active UPA 15 mg QD (N=114) n (%)	Japan Active UPA 30 mg QD (N=115) n (%)	Overall Placebo (N=868) n (%)	Overall Active UPA 15 mg QD (N=866) n (%)	Overall Active UPA 30 mg QD (N=873) n (%)
Any adverse event	0	0	0	0	1 (0.1)	0
腎および尿路障害	0	0	0	0	1 (0.1)	0
急性腎障害	0	0	0	0	1 (0.1)	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or up to 30 days after the last dose of study drug in DB Period, whichever occurs first.
Subjects are counted once in each row, regardless of the number of events they may have had.
The sum of the total number of subjects reporting each of the preferred terms should be greater than or equal to the system organ class total.
A subject who reports two or more different preferred terms which are in the same system organ class is counted only once in the system organ class total.

相互参照：ISS Table 2.4　1.6.7.16

表 2.7.4.7-109. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の 100 人年あたりの腎機能障害の発現率（全体集団及び日本人集団）

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=135.8) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=137.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1371) (PYS=955.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1378) (PYS=974.2) Events (E/100PY)
Any adverse event	0	0	1 (0.1)	1 (0.1)
腎および尿路障害	0	0	1 (0.1)	1 (0.1)
急性腎障害	0	0	1 (0.1)	1 (0.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：ISS Table 2.4　2.4.1.16

表 2.7.4.7-110. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の青少年被験者及び成人被験者の 100 人年あたりの腎機能障害の発現率（全体集団及び日本人集団）

Subgroup: Adolescent

	Japan		Overall	
MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=16) (PYS=11.7) Events (E/100PY)	UPA 30 mg QD (N=16) (PYS=11.3) Events (E/100PY)	UPA 15 mg QD (N=181) (PYS=132.5) Events (E/100PY)	UPA 30 mg QD (N=180) (PYS=134.1) Events (E/100PY)
Any adverse event	0	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

Subgroup: Adult

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=161) (PYS=124.1) Events (E/100PY)	Japan UPA 30 mg QD (N=165) (PYS=126.0) Events (E/100PY)	Overall UPA 15 mg QD (N=1190) (PYS=822.4) Events (E/100PY)	Overall UPA 30 mg QD (N=1198) (PYS=840.1) Events (E/100PY)
Any adverse event	0	0	1 (0.1)	1 (0.1)
腎および尿路障害	0	0	1 (0.1)	1 (0.1)
急性腎障害	0	0	1 (0.1)	1 (0.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：ISS Table 2.4　2.9.5.16

表 2.7.4.7-111. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の 100 人年あたりの腎機能障害の発現率（全体集団及び日本人集団，更新時）

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=177) (PYS=225.5) Events (E/100PY)	Japan UPA 30 mg QD (N=181) (PYS=228.3) Events (E/100PY)	Overall UPA 15 mg QD (N=1372) (PYS=1407.0) Events (E/100PY)	Overall UPA 30 mg QD (N=1380) (PYS=1446.5) Events (E/100PY)
Any adverse event	0	0	1 (<0.1)	2 (0.1)
腎および尿路障害	0	0	1 (<0.1)	2 (0.1)
急性腎障害	0	0	1 (<0.1)	1 (<0.1)
腎不全	0	0	0	1 (<0.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：Updated ISS Table 2.4　2.4.1.16

表 2.7.4.7-112. 長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の青少年被験者及び成人被験者の 100 人年あたりの腎機能障害の発現率（全体集団及び日本人集団，更新時）

	---------- Japan ----------		---------- Overall ----------	
MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=16) (PYS=19.9) Events (E/100PY)	UPA 30 mg QD (N=16) (PYS=18.3) Events (E/100PY)	UPA 15 mg QD (N=181) (PYS=194.3) Events (E/100PY)	UPA 30 mg QD (N=180) (PYS=197.0) Events (E/100PY)
Subgroup: Adolescent				
Any adverse event	0	0	0	0

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

MedDRA 22.1 System Organ Class Preferred Term	Japan UPA 15 mg QD (N=161) (PYS=205.6) Events (E/100PY)	Japan UPA 30 mg QD (N=165) (PYS=210.0) Events (E/100PY)	Overall UPA 15 mg QD (N=1191) (PYS=1212.7) Events (E/100PY)	Overall UPA 30 mg QD (N=1200) (PYS=1249.5) Events (E/100PY)
Subgroup: Adult				
Any adverse event	0	0	1 (<0.1)	2 (0.2)
腎および尿路障害	0	0	1 (<0.1)	2 (0.2)
急性腎障害	0	0	1 (<0.1)	1 (<0.1)
腎不全	0	0	0	1 (<0.1)

Note: Treatment-emergent adverse events are defined as any adverse events with an onset 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.

相互参照：Updated ISS Table 2.4　2.9.5.16

表 2.7.4.7-113.　投与 16 週時までの曝露状況（Safety_DB_M 集団，日本人集団）：M16-045 試験

	Placebo (N=14)	Active: UPA 15 mg QD (N=15)	Active: UPA 30 mg QD (N=16)	Total (N=31)
Duration (days)				
n	14	15	16	31
Mean (SD)	73.6 (49.54)	112.1 (1.60)	102.6 (26.13)	107.2 (19.13)
Median	110.0	112.0	112.0	112.0
Min, Max	5, 113	109, 115	16, 114	16, 115

Note: For subjects who did not continue into BE Period, duration is defined as date of last dose of study drug in DB Period - date of first dose of study drug in DB Period + 1; For subjects who continued into BE Period, duration is defined as the minimum of (date of first dose of study drug in BE Period - date of first dose of study drug in DB Period) and (date of last dose of study drug in DB Period - date of first dose of study drug in DB Period + 1).

相互参照：M16-045 試験 W16 Japan data Table 14.1　8.1.1_J

表 2.7.4.7-114.　投与 52 週時データカットオフまでの曝露状況（ALL_UPA_M 集団，日本人集団）：M16-045 試験

	UPA 15 mg QD (N=20)	UPA 30 mg QD (N=19)	Total (N=39)
Duration (days)			
n	20	19	39
Mean (SD)	584.9 (172.67)	596.2 (213.24)	590.4 (190.99)
Median	606.0	662.0	623.0
Min, Max	190, 789	16, 797	16, 797
Duration (weeks)			
>= 4 weeks	20 (100)	18 (94.7)	38 (97.4)
>= 12 weeks	20 (100)	17 (89.5)	37 (94.9)
>= 24 weeks	20 (100)	17 (89.5)	37 (94.9)
>= 36 weeks	18 (90.0)	17 (89.5)	35 (89.7)
>= 48 weeks	18 (90.0)	17 (89.5)	35 (89.7)
>= 52 weeks	18 (90.0)	17 (89.5)	35 (89.7)
>= 72 weeks	15 (75.0)	15 (78.9)	30 (76.9)
>= 104 weeks	6 (30.0)	4 (21.1)	10 (25.6)
>= 130 weeks	0	0	0

Note: Duration of treatment = The date of last dose of upadacitinib - the date of first dose of upadacitinib + 1.

相互参照：M16-045 試験 W52 Japan data Table 14.1　7.2.1_J

表 2.7.4.7-115.　投与 16 週時までの全有害事象の集計表（Safety_DB_M 集団，日本人集団）：M16-045 試験

MedDRA 22.1 System Organ Class Preferred Term	Placebo (N=14) n (%)	Active UPA 15 mg QD (N=15) n (%)	Active UPA 30 mg QD (N=16) n (%)	Total (N=31) n (%)
Any adverse event	9 (64.3)	10 (66.7)	12 (75.0)	22 (71.0)
内分泌障害	0	0	1 (6.3)	1 (3.2)
バセドウ病	0	0	1 (6.3)	1 (3.2)
眼障害	1 (7.1)	0	0	0
アレルギー性結膜炎	1 (7.1)	0	0	0
胃腸障害	0	2 (13.3)	3 (18.8)	5 (16.1)
上腹部痛	0	0	2 (12.5)	2 (6.5)
齲歯	0	1 (6.7)	0	1 (3.2)
下痢	0	1 (6.7)	1 (6.3)	2 (6.5)
悪心	0	0	1 (6.3)	1 (3.2)
一般・全身障害および投与部位の状態	0	0	2 (12.5)	2 (6.5)
顔面浮腫	0	0	1 (6.3)	1 (3.2)
発熱	0	0	1 (6.3)	1 (3.2)
感染症および寄生虫症	5 (35.7)	8 (53.3)	9 (56.3)	17 (54.8)
蜂巣炎	1 (7.1)	0	0	0
毛包炎	1 (7.1)	0	1 (6.3)	1 (3.2)
陰部単純ヘルペス	0	0	1 (6.3)	1 (3.2)

Note: Treatment-emergent adverse events in DB Period are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or no more than 30 days after the last dose of study drug in DB Period, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.

MedDRA 22.1 System Organ Class Preferred Term	Placebo (N=14) n (%)	Active UPA 15 mg QD (N=15) n (%)	Active UPA 30 mg QD (N=16) n (%)	Total (N=31) n (%)
感染症および寄生虫症 (Cont.)				
単純ヘルペス	1 (7.1)	1 (6.7)	1 (6.3)	2 (6.5)
帯状疱疹	0	1 (6.7)	0	1 (3.2)
膿痂疹	1 (7.1)	0	0	0
感染性皮膚嚢腫	1 (7.1)	0	0	0
インフルエンザ	0	2 (13.3)	1 (6.3)	3 (9.7)
カポジ水痘様発疹	1 (7.1)	0	0	0
上咽頭炎	1 (7.1)	3 (20.0)	7 (43.8)	10 (32.3)
口腔ヘルペス	1 (7.1)	0	1 (6.3)	1 (3.2)
爪囲炎	1 (7.1)	0	0	0
咽頭炎	0	1 (6.7)	0	1 (3.2)
膿皮症	0	1 (6.7)	0	1 (3.2)
皮膚感染	0	0	1 (6.3)	1 (3.2)
神経系障害	1 (7.1)	0	1 (6.3)	1 (3.2)
頭痛	1 (7.1)	0	1 (6.3)	1 (3.2)
呼吸器、胸郭および縦隔障害	1 (7.1)	0	0	0
喘息	1 (7.1)	0	0	0

Note: Treatment-emergent adverse events in DB Period are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or no more than 30 days after the last dose of study drug in DB Period, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.

MedDRA 22.1 System Organ Class Preferred Term	Placebo (N=14) n (%)	Active UPA 15 mg QD (N=15) n (%)	Active UPA 30 mg QD (N=16) n (%)	Total (N=31) n (%)
皮膚および皮下組織障害	9 (64.3)	3 (20.0)	5 (31.3)	8 (25.8)
ざ瘡	1 (7.1)	1 (6.7)	4 (25.0)	5 (16.1)
ざ瘡様皮膚炎	0	0	1 (6.3)	1 (3.2)
アトピー性皮膚炎	6 (42.9)	2 (13.3)	0	2 (6.5)
接触皮膚炎	0	0	1 (6.3)	1 (3.2)
紅斑	1 (7.1)	0	1 (6.3)	1 (3.2)
過角化	1 (7.1)	0	0	0

Note: Treatment-emergent adverse events in DB Period are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or no more than 30 days after the last dose of study drug in DB Period, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.

相互参照：M16-045 試験 W16 Japan data Table 14.3 1.6.1.1 J

表 2.7.4.7-116.　投与 16 週時までの治験薬と関連ありの有害事象の基本語別の集計表（Safety_DB_M 集団，日本人集団）：M16-045 試験

MedDRA 22.1 System Organ Class Preferred Term	Placebo (N=14) n (%)	Active UPA 15 mg QD (N=15) n (%)	Active UPA 30 mg QD (N=16) n (%)	Total (N=31) n (%)
Any adverse event	3 (21.4)	3 (20.0)	6 (37.5)	9 (29.0)
胃腸障害	0	0	1 (6.3)	1 (3.2)
下痢	0	0	1 (6.3)	1 (3.2)
悪心	0	0	1 (6.3)	1 (3.2)
一般・全身障害および投与部位の状態	0	0	1 (6.3)	1 (3.2)
顔面浮腫	0	0	1 (6.3)	1 (3.2)
感染症および寄生虫症	2 (14.3)	2 (13.3)	3 (18.8)	5 (16.1)
毛包炎	0	0	1 (6.3)	1 (3.2)
単純ヘルペス	0	1 (6.7)	1 (6.3)	2 (6.5)
帯状疱疹	0	1 (6.7)	0	1 (3.2)
膿痂疹	1 (7.1)	0	0	0
カポジ水痘様発疹	1 (7.1)	0	0	0
口腔ヘルペス	1 (7.1)	0	1 (6.3)	1 (3.2)
神経系障害	1 (7.1)	0	1 (6.3)	1 (3.2)
頭痛	1 (7.1)	0	1 (6.3)	1 (3.2)
皮膚および皮下組織障害	3 (21.4)	1 (6.7)	2 (12.5)	3 (9.7)
ざ瘡	0	1 (6.7)	1 (6.3)	2 (6.5)

Note: Treatment-emergent adverse events in DB Period are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or no more than 30 days after the last dose of study drug in DB Period, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.

MedDRA 22.1 System Organ Class Preferred Term	Placebo (N=14) n (%)	Active UPA 15 mg QD (N=15) n (%)	Active UPA 30 mg QD (N=16) n (%)	Total (N=31) n (%)
皮膚および皮下組織障害 (Cont.)				
アトピー性皮膚炎	2 (14.3)	0	0	0
紅斑	1 (7.1)	0	1 (6.3)	1 (3.2)

Note: Treatment-emergent adverse events in DB Period are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or no more than 30 days after the last dose of study drug in DB Period, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.

相互参照：M16-045 試験 W16 Japan data Table 14.3 1.10.1 J

表 2.7.4.7-117. 投与 16 週時までの重症度別の有害事象の基本語別の集計表（Safety_DB_M 集団，日本人集団）：M16-045 試験

MedDRA 22.1 System Organ Class Preferred Term Toxicity	Placebo (N=14) n (%)	Active UPA 15 mg QD (N=15) n (%)	Active UPA 30 mg QD (N=16) n (%)	Total (N=31) n (%)
Any adverse event	9 (64.3)	10 (66.7)	12 (75.0)	22 (71.0)
Grade 1	2 (14.3)	3 (20.0)	4 (25.0)	7 (22.6)
Grade 2	5 (35.7)	7 (46.7)	7 (43.8)	14 (45.2)
Grade 3	2 (14.3)	0	1 (6.3)	1 (3.2)
内分泌障害	0	0	1 (6.3)	1 (3.2)
Grade 2	0	0	1 (6.3)	1 (3.2)
バセドウ病	0	0	1 (6.3)	1 (3.2)
Grade 2	0	0	1 (6.3)	1 (3.2)
眼障害	1 (7.1)	0	0	0
Grade 1	1 (7.1)	0	0	0
アレルギー性結膜炎	1 (7.1)	0	0	0
Grade 1	1 (7.1)	0	0	0
胃腸障害	0	2 (13.3)	3 (18.8)	5 (16.1)
Grade 1	0	0	2 (12.5)	2 (6.5)

Note: Treatment-emergent adverse events in DB Period are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or no more than 30 days after the last dose of study drug in DB Period, whichever occurs firstly.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	Placebo (N=14) n (%)	Active UPA 15 mg QD (N=15) n (%)	Active UPA 30 mg QD (N=16) n (%)	Total (N=31) n (%)
胃腸障害 (Cont.)				
Grade 2	0	2 (13.3)	1 (6.3)	3 (9.7)
上腹部痛	0	0	2 (12.5)	2 (6.5)
Grade 1	0	0	2 (12.5)	2 (6.5)
齲歯	0	1 (6.7)	0	1 (3.2)
Grade 2	0	1 (6.7)	0	1 (3.2)
下痢	0	1 (6.7)	1 (6.3)	2 (6.5)
Grade 2	0	1 (6.7)	1 (6.3)	2 (6.5)
悪心	0	0	1 (6.3)	1 (3.2)
Grade 2	0	0	1 (6.3)	1 (3.2)
一般・全身障害および投与部位の状態	0	0	2 (12.5)	2 (6.5)
Grade 1	0	0	1 (6.3)	1 (3.2)
Grade 2	0	0	1 (6.3)	1 (3.2)
顔面浮腫	0	0	1 (6.3)	1 (3.2)
Grade 2	0	0	1 (6.3)	1 (3.2)

Note: Treatment-emergent adverse events in DB Period are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or no more than 30 days after the last dose of study drug in DB Period, whichever occurs firstly.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	Placebo (N=14) n (%)	Active UPA 15 mg QD (N=15) n (%)	Active UPA 30 mg QD (N=16) n (%)	Total (N=31) n (%)
一般・全身障害および投与部位の状態 (Cont.)				
発熱	0	0	1 (6.3)	1 (3.2)
Grade 1	0	0	1 (6.3)	1 (3.2)
感染症および寄生虫症	5 (35.7)	8 (53.3)	9 (56.3)	17 (54.8)
Grade 1	2 (14.3)	4 (26.7)	4 (25.0)	8 (25.8)
Grade 2	3 (21.4)	4 (26.7)	5 (31.3)	9 (29.0)
蜂巣炎	1 (7.1)	0	0	0
Grade 2	1 (7.1)	0	0	0
毛包炎	1 (7.1)	0	1 (6.3)	1 (3.2)
Grade 1	1 (7.1)	0	1 (6.3)	1 (3.2)
陰部単純ヘルペス	0	0	1 (6.3)	1 (3.2)
Grade 2	0	0	1 (6.3)	1 (3.2)
単純ヘルペス	1 (7.1)	1 (6.7)	1 (6.3)	2 (6.5)
Grade 1	0	1 (6.7)	0	1 (3.2)
Grade 2	1 (7.1)	0	1 (6.3)	1 (3.2)

Note: Treatment-emergent adverse events in DB Period are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or no more than 30 days after the last dose of study drug in DB Period, whichever occurs firstly.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	Placebo (N=14) n (%)	Active UPA 15 mg QD (N=15) n (%)	Active UPA 30 mg QD (N=16) n (%)	Total (N=31) n (%)
感染症および寄生虫症 (Cont.)				
帯状疱疹	0	1 (6.7)	0	1 (3.2)
Grade 2	0	1 (6.7)	0	1 (3.2)
膿痂疹	1 (7.1)	0	0	0
Grade 2	1 (7.1)	0	0	0
感染性皮膚嚢腫	1 (7.1)	0	0	0
Grade 2	1 (7.1)	0	0	0
インフルエンザ	0	2 (13.3)	1 (6.3)	3 (9.7)
Grade 1	0	0	1 (6.3)	1 (3.2)
Grade 2	0	2 (13.3)	0	2 (6.5)
カポジ水痘様発疹	1 (7.1)	0	0	0
Grade 2	1 (7.1)	0	0	0
上咽頭炎	1 (7.1)	3 (20.0)	7 (43.8)	10 (32.3)
Grade 1	1 (7.1)	2 (13.3)	4 (25.0)	6 (19.4)
Grade 2	0	1 (6.7)	3 (18.8)	4 (12.9)

Note: Treatment-emergent adverse events in DB Period are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or no more than 30 days after the last dose of study drug in DB Period, whichever occurs firstly.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	Placebo (N=14) n (%)	Active UPA 15 mg QD (N=15) n (%)	Active UPA 30 mg QD (N=16) n (%)	Total (N=31) n (%)
感染症および寄生虫症 (Cont.)				
口腔ヘルペス	1 (7.1)	0	1 (6.3)	1 (3.2)
Grade 1	0	0	1 (6.3)	1 (3.2)
Grade 2	1 (7.1)	0	0	0
爪囲炎	1 (7.1)	0	0	0
Grade 1	1 (7.1)	0	0	0
咽頭炎	0	1 (6.7)	0	1 (3.2)
Grade 1	0	1 (6.7)	0	1 (3.2)
膿皮症	0	1 (6.7)	0	1 (3.2)
Grade 1	0	1 (6.7)	0	1 (3.2)
皮膚感染	0	0	1 (6.3)	1 (3.2)
Grade 2	0	0	1 (6.3)	1 (3.2)
神経系障害	1 (7.1)	0	1 (6.3)	1 (3.2)
Grade 1	1 (7.1)	0	1 (6.3)	1 (3.2)

Note: Treatment-emergent adverse events in DB Period are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or no more than 30 days after the last dose of study drug in DB Period, whichever occurs firstly.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	Placebo (N=14) n (%)	Active UPA 15 mg QD (N=15) n (%)	Active UPA 30 mg QD (N=16) n (%)	Total (N=31) n (%)
神経系障害 (Cont.)				
頭痛	1 (7.1)	0	1 (6.3)	1 (3.2)
Grade 1	1 (7.1)	0	1 (6.3)	1 (3.2)
呼吸器、胸郭および縦隔障害	1 (7.1)	0	0	0
Grade 1	1 (7.1)	0	0	0
喘息	1 (7.1)	0	0	0
Grade 1	1 (7.1)	0	0	0
皮膚および皮下組織障害	9 (64.3)	3 (20.0)	5 (31.3)	8 (25.8)
Grade 1	2 (14.3)	0	1 (6.3)	1 (3.2)
Grade 2	5 (35.7)	3 (20.0)	3 (18.8)	6 (19.4)
Grade 3	2 (14.3)	0	1 (6.3)	1 (3.2)
ざ瘡	1 (7.1)	1 (6.7)	4 (25.0)	5 (16.1)
Grade 1	0	0	1 (6.3)	1 (3.2)
Grade 2	1 (7.1)	1 (6.7)	3 (18.8)	4 (12.9)
ざ瘡様皮膚炎	0	0	1 (6.3)	1 (3.2)
Grade 2	0	0	1 (6.3)	1 (3.2)

Note: Treatment-emergent adverse events in DB Period are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or no more than 30 days after the last dose of study drug in DB Period, whichever occurs firstly.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	Placebo (N=14) n (%)	Active UPA 15 mg QD (N=15) n (%)	Active UPA 30 mg QD (N=16) n (%)	Total (N=31) n (%)
皮膚および皮下組織障害 (Cont.)				
アトピー性皮膚炎	6 (42.9)	2 (13.3)	0	2 (6.5)
Grade 1	1 (7.1)	0	0	0
Grade 2	3 (21.4)	2 (13.3)	0	2 (6.5)
Grade 3	2 (14.3)	0	0	0
接触皮膚炎	0	0	1 (6.3)	1 (3.2)
Grade 3	0	0	1 (6.3)	1 (3.2)
紅斑	1 (7.1)	0	1 (6.3)	1 (3.2)
Grade 2	1 (7.1)	0	1 (6.3)	1 (3.2)
過角化	1 (7.1)	0	0	0
Grade 1	1 (7.1)	0	0	0

Note: Treatment-emergent adverse events in DB Period are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or no more than 30 days after the last dose of study drug in DB Period, whichever occurs firstly.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

相互参照：M16-045 試験 W16 Japan data Table 14.3 1.11.1 J

表 2.7.4.7-118.　投与 52 週時データカットオフまでの全有害事象の集計表（ALL_UPA_M 集団，日本人集団）：M16-045 試験

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=20) n (%)	UPA 30 mg QD (N=19) n (%)	Total (N=39) n (%)
Any adverse event	19 (95.0)	18 (94.7)	37 (94.9)
血液およびリンパ系障害	1 (5.0)	1 (5.3)	2 (5.1)
リンパ節症	1 (5.0)	0	1 (2.6)
脾腫	0	1 (5.3)	1 (2.6)
耳および迷路障害	0	2 (10.5)	2 (5.1)
突発性難聴	0	1 (5.3)	1 (2.6)
鼓膜障害	0	1 (5.3)	1 (2.6)
内分泌障害	0	1 (5.3)	1 (2.6)
バセドウ病	0	1 (5.3)	1 (2.6)
眼障害	1 (5.0)	2 (10.5)	3 (7.7)
眼瞼炎	0	1 (5.3)	1 (2.6)
眼窩周囲腫脹	0	1 (5.3)	1 (2.6)
網膜剥離	1 (5.0)	0	1 (2.6)
胃腸障害	3 (15.0)	6 (31.6)	9 (23.1)
腹痛	0	2 (10.5)	2 (5.1)
上腹部痛	0	2 (10.5)	2 (5.1)
慢性胃炎	1 (5.0)	0	1 (2.6)

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

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=20) n (%)	UPA 30 mg QD (N=19) n (%)	Total (N=39) n (%)
胃腸障害 (Cont.)			
齲歯	1 (5.0)	1 (5.3)	2 (5.1)
下痢	1 (5.0)	1 (5.3)	2 (5.1)
胃食道逆流性疾患	1 (5.0)	0	1 (2.6)
痔核	0	1 (5.3)	1 (2.6)
裂孔ヘルニア	1 (5.0)	0	1 (2.6)
悪心	0	1 (5.3)	1 (2.6)
一般・全身障害および投与部位の状態	2 (10.0)	2 (10.5)	4 (10.3)
顔面浮腫	1 (5.0)	1 (5.3)	2 (5.1)
発熱	1 (5.0)	1 (5.3)	2 (5.1)
肝胆道系障害	1 (5.0)	2 (10.5)	3 (7.7)
胆石症	0	1 (5.3)	1 (2.6)
肝機能異常	0	1 (5.3)	1 (2.6)
脂肪肝	1 (5.0)	1 (5.3)	2 (5.1)
感染症および寄生虫症	14 (70.0)	14 (73.7)	28 (71.8)
蜂巣炎	1 (5.0)	0	1 (2.6)
膀胱炎	0	2 (10.5)	2 (5.1)
丹毒	0	1 (5.3)	1 (2.6)

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

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=20) n (%)	UPA 30 mg QD (N=19) n (%)	Total (N=39) n (%)
感染症および寄生虫症 (Cont.)			
毛包炎	1 (5.0)	4 (21.1)	5 (12.8)
胃腸炎	0	1 (5.3)	1 (2.6)
陰部単純ヘルペス	0	1 (5.3)	1 (2.6)
ヘルペス眼感染	0	1 (5.3)	1 (2.6)
単純ヘルペス	2 (10.0)	3 (15.8)	5 (12.8)
帯状疱疹	3 (15.0)	2 (10.5)	5 (12.8)
感染性皮膚嚢腫	0	1 (5.3)	1 (2.6)
インフルエンザ	2 (10.0)	1 (5.3)	3 (7.7)
カポジ水痘様発疹	2 (10.0)	4 (21.1)	6 (15.4)
伝染性軟属腫	0	1 (5.3)	1 (2.6)
上咽頭炎	6 (30.0)	7 (36.8)	13 (33.3)
口腔ヘルペス	1 (5.0)	1 (5.3)	2 (5.1)
外耳炎	1 (5.0)	1 (5.3)	2 (5.1)
中耳炎	0	1 (5.3)	1 (2.6)
爪囲炎	1 (5.0)	1 (5.3)	2 (5.1)
咽頭炎	1 (5.0)	0	1 (2.6)
膿皮症	1 (5.0)	0	1 (2.6)

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

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=20) n (%)	UPA 30 mg QD (N=19) n (%)	Total (N=39) n (%)
感染症および寄生虫症 (Cont.)			
副鼻腔炎	0	1 (5.3)	1 (2.6)
皮膚感染	0	2 (10.5)	2 (5.1)
足部白癬	1 (5.0)	0	1 (2.6)
扁桃炎	0	2 (10.5)	2 (5.1)
傷害、中毒および処置合併症	4 (20.0)	3 (15.8)	7 (17.9)
節足動物咬傷	2 (10.0)	0	2 (5.1)
挫傷	0	1 (5.3)	1 (2.6)
足骨折	1 (5.0)	0	1 (2.6)
皮膚擦過傷	1 (5.0)	0	1 (2.6)
皮膚裂傷	0	1 (5.3)	1 (2.6)
ストレス骨折	0	1 (5.3)	1 (2.6)
熱傷	0	1 (5.3)	1 (2.6)
臨床検査	3 (15.0)	3 (15.8)	6 (15.4)
アラニンアミノトランスフェラーゼ増加	1 (5.0)	1 (5.3)	2 (5.1)
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (5.3)	1 (2.6)
血中クレアチンホスホキナーゼ増加	0	3 (15.8)	3 (7.7)
血中クレアチニン増加	1 (5.0)	0	1 (2.6)

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

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=20) n (%)	UPA 30 mg QD (N=19) n (%)	Total (N=39) n (%)
臨床検査 (Cont.)			
血中免疫グロブリンE増加	1 (5.0)	0	1 (2.6)
ケモカイン増加	1 (5.0)	0	1 (2.6)
筋骨格系および結合組織障害	1 (5.0)	3 (15.8)	4 (10.3)
背部痛	0	2 (10.5)	2 (5.1)
足変形	1 (5.0)	0	1 (2.6)
筋骨格系胸痛	0	1 (5.3)	1 (2.6)
筋骨格痛	0	1 (5.3)	1 (2.6)
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）	2 (10.0)	2 (10.5)	4 (10.3)
乳癌	1 (5.0)	0	1 (2.6)
結腸癌	1 (5.0)	0	1 (2.6)
皮膚乳頭腫	1 (5.0)	2 (10.5)	3 (7.7)
神経系障害	0	1 (5.3)	1 (2.6)
頭痛	0	1 (5.3)	1 (2.6)
精神障害	1 (5.0)	0	1 (2.6)
睡眠障害	1 (5.0)	0	1 (2.6)
腎および尿路障害	1 (5.0)	1 (5.3)	2 (5.1)
腎結石症	0	1 (5.3)	1 (2.6)

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

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=20) n (%)	UPA 30 mg QD (N=19) n (%)	Total (N=39) n (%)
腎および尿路障害 (Cont.)			
尿路障害	1 (5.0)	0	1 (2.6)
生殖系および乳房障害	1 (5.0)	0	1 (2.6)
月経困難症	1 (5.0)	0	1 (2.6)
呼吸器、胸郭および縦隔障害	0	2 (10.5)	2 (5.1)
喘息	0	1 (5.3)	1 (2.6)
アレルギー性鼻炎	0	1 (5.3)	1 (2.6)
上気道の炎症	0	1 (5.3)	1 (2.6)
声帯肥厚	0	1 (5.3)	1 (2.6)
皮膚および皮下組織障害	12 (60.0)	11 (57.9)	23 (59.0)
ざ瘡	2 (10.0)	5 (26.3)	7 (17.9)
皮膚嚢腫	0	1 (5.3)	1 (2.6)
ざ瘡様皮膚炎	0	2 (10.5)	2 (5.1)
アトピー性皮膚炎	11 (55.0)	6 (31.6)	17 (43.6)
接触皮膚炎	1 (5.0)	2 (10.5)	3 (7.7)
湿疹	0	1 (5.3)	1 (2.6)
紅斑	0	1 (5.3)	1 (2.6)
そう痒症	2 (10.0)	0	2 (5.1)

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

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=20) n (%)	UPA 30 mg QD (N=19) n (%)	Total (N=39) n (%)
皮膚および皮下組織障害 (Cont.)			
黄色板腫	1 (5.0)	0	1 (2.6)

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

相互参照：M16-045 試験 W52 Japan data Table 14.3 1.5.1.1 J

表 2.7.4.7-119.　投与 52 週時データカットオフまでの 100 人年あたりの全有害事象の集計表（ALL_UPA_M 集団，日本人集団）：M16-045 試験

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=20) (PYS=32.0) Events (E/100PY)	UPA 30 mg QD (N=19) (PYS=31.0) Events (E/100PY)	Total (N=39) (PYS=63.0) Events (E/100PY)
Any adverse event	66 (206.1)	113 (364.4)	179 (284.0)
血液およびリンパ系障害	1 (3.1)	1 (3.2)	2 (3.2)
リンパ節症	1 (3.1)	0	1 (1.6)
脾腫	0	1 (3.2)	1 (1.6)
耳および迷路障害	0	2 (6.4)	2 (3.2)
突発性難聴	0	1 (3.2)	1 (1.6)
鼓膜障害	0	1 (3.2)	1 (1.6)
内分泌障害	0	1 (3.2)	1 (1.6)
バセドウ病	0	1 (3.2)	1 (1.6)
眼障害	1 (3.1)	2 (6.4)	3 (4.8)
眼瞼炎	0	1 (3.2)	1 (1.6)
眼窩周囲腫脹	0	1 (3.2)	1 (1.6)
網膜剥離	1 (3.1)	0	1 (1.6)
胃腸障害	5 (15.6)	9 (29.0)	14 (22.2)
腹痛	0	2 (6.4)	2 (3.2)
上腹部痛	0	2 (6.4)	2 (3.2)
慢性胃炎	1 (3.1)	0	1 (1.6)

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.

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=20) (PYS=32.0) Events (E/100PY)	UPA 30 mg QD (N=19) (PYS=31.0) Events (E/100PY)	Total (N=39) (PYS=63.0) Events (E/100PY)
胃腸障害 (Cont.)			
齲歯	1 (3.1)	1 (3.2)	2 (3.2)
下痢	1 (3.1)	1 (3.2)	2 (3.2)
胃食道逆流性疾患	1 (3.1)	0	1 (1.6)
痔核	0	2 (6.4)	2 (3.2)
裂孔ヘルニア	1 (3.1)	0	1 (1.6)
悪心	0	1 (3.2)	1 (1.6)
一般・全身障害および投与部位の状態	2 (6.2)	2 (6.4)	4 (6.3)
顔面浮腫	1 (3.1)	1 (3.2)	2 (3.2)
発熱	1 (3.1)	1 (3.2)	2 (3.2)
肝胆道系障害	1 (3.1)	4 (12.9)	5 (7.9)
胆石症	0	1 (3.2)	1 (1.6)
肝機能異常	0	2 (6.4)	2 (3.2)
脂肪肝	1 (3.1)	1 (3.2)	2 (3.2)
感染症および寄生虫症	24 (74.9)	50 (161.2)	74 (117.4)
蜂巣炎	1 (3.1)	0	1 (1.6)
膀胱炎	0	2 (6.4)	2 (3.2)
丹毒	0	1 (3.2)	1 (1.6)

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.

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=20) (PYS=32.0) Events (E/100PY)	UPA 30 mg QD (N=19) (PYS=31.0) Events (E/100PY)	Total (N=39) (PYS=63.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)			
毛包炎	1 (3.1)	4 (12.9)	5 (7.9)
胃腸炎	0	1 (3.2)	1 (1.6)
陰部単純ヘルペス	0	2 (6.4)	2 (3.2)
ヘルペス眼感染	0	4 (12.9)	4 (6.3)
単純ヘルペス	2 (6.2)	5 (16.1)	7 (11.1)
帯状疱疹	3 (9.4)	2 (6.4)	5 (7.9)
感染性皮膚嚢腫	0	1 (3.2)	1 (1.6)
インフルエンザ	2 (6.2)	1 (3.2)	3 (4.8)
カポジ水痘様発疹	2 (6.2)	5 (16.1)	7 (11.1)
伝染性軟属腫	0	1 (3.2)	1 (1.6)
上咽頭炎	6 (18.7)	9 (29.0)	15 (23.8)
口腔ヘルペス	1 (3.1)	1 (3.2)	2 (3.2)
外耳炎	1 (3.1)	2 (6.4)	3 (4.8)
中耳炎	0	1 (3.2)	1 (1.6)
爪囲炎	1 (3.1)	1 (3.2)	2 (3.2)
咽頭炎	2 (6.2)	0	2 (3.2)
膿皮症	1 (3.1)	0	1 (1.6)

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.

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=20) (PYS=32.0) Events (E/100PY)	UPA 30 mg QD (N=19) (PYS=31.0) Events (E/100PY)	Total (N=39) (PYS=63.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)			
副鼻腔炎	0	1 (3.2)	1 (1.6)
皮膚感染	0	2 (6.4)	2 (3.2)
足部白癬	1 (3.1)	0	1 (1.6)
扁桃炎	0	4 (12.9)	4 (6.3)
傷害、中毒および処置合併症	4 (12.5)	5 (16.1)	9 (14.3)
節足動物咬傷	2 (6.2)	0	2 (3.2)
挫傷	0	1 (3.2)	1 (1.6)
足骨折	1 (3.1)	0	1 (1.6)
皮膚擦過傷	1 (3.1)	0	1 (1.6)
皮膚裂傷	0	1 (3.2)	1 (1.6)
ストレス骨折	0	2 (6.4)	2 (3.2)
熱傷	0	1 (3.2)	1 (1.6)
臨床検査	4 (12.5)	5 (16.1)	9 (14.3)
アラニンアミノトランスフェラーゼ増加	1 (3.1)	1 (3.2)	2 (3.2)
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (3.2)	1 (1.6)
血中クレアチンホスホキナーゼ増加	0	3 (9.7)	3 (4.8)
血中クレアチニン増加	1 (3.1)	0	1 (1.6)

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.

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=20) (PYS=32.0) Events (E/100PY)	UPA 30 mg QD (N=19) (PYS=31.0) Events (E/100PY)	Total (N=39) (PYS=63.0) Events (E/100PY)
臨床検査 (Cont.)			
血中免疫グロブリンE増加	1 (3.1)	0	1 (1.6)
ケモカイン増加	1 (3.1)	0	1 (1.6)
筋骨格系および結合組織障害	1 (3.1)	4 (12.9)	5 (7.9)
背部痛	0	2 (6.4)	2 (3.2)
足変形	1 (3.1)	0	1 (1.6)
筋骨格系胸痛	0	1 (3.2)	1 (1.6)
筋骨格痛	0	1 (3.2)	1 (1.6)
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）	3 (9.4)	2 (6.4)	5 (7.9)
乳癌	1 (3.1)	0	1 (1.6)
結腸癌	1 (3.1)	0	1 (1.6)
皮膚乳頭腫	1 (3.1)	2 (6.4)	3 (4.8)
神経系障害	0	1 (3.2)	1 (1.6)
頭痛	0	1 (3.2)	1 (1.6)
精神障害	1 (3.1)	0	1 (1.6)
睡眠障害	1 (3.1)	0	1 (1.6)
腎および尿路障害	1 (3.1)	1 (3.2)	2 (3.2)
腎結石症	0	1 (3.2)	1 (1.6)

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.

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=20) (PYS=32.0) Events (E/100PY)	UPA 30 mg QD (N=19) (PYS=31.0) Events (E/100PY)	Total (N=39) (PYS=63.0) Events (E/100PY)
腎および尿路障害 (Cont.)			
尿路障害	1 (3.1)	0	1 (1.6)
生殖系および乳房障害	1 (3.1)	0	1 (1.6)
月経困難症	1 (3.1)	0	1 (1.6)
呼吸器、胸郭および縦隔障害	0	5 (16.1)	5 (7.9)
喘息	0	2 (6.4)	2 (3.2)
アレルギー性鼻炎	0	1 (3.2)	1 (1.6)
上気道の炎症	0	1 (3.2)	1 (1.6)
声帯肥厚	0	1 (3.2)	1 (1.6)
皮膚および皮下組織障害	17 (53.1)	19 (61.3)	36 (57.1)
ざ瘡	2 (6.2)	6 (19.3)	8 (12.7)
皮膚嚢腫	0	1 (3.2)	1 (1.6)
ざ瘡様皮膚炎	0	2 (6.4)	2 (3.2)
アトピー性皮膚炎	11 (34.3)	6 (19.3)	17 (27.0)
接触皮膚炎	1 (3.1)	2 (6.4)	3 (4.8)
湿疹	0	1 (3.2)	1 (1.6)
紅斑	0	1 (3.2)	1 (1.6)
そう痒症	2 (6.2)	0	2 (3.2)

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.

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=20) (PYS=32.0) Events (E/100PY)	UPA 30 mg QD (N=19) (PYS=31.0) Events (E/100PY)	Total (N=39) (PYS=63.0) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)			
黄色板腫	1 (3.1)	0	1 (1.6)

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.

相互参照：M16-045 試験 W52 Japan data Table 14.3 1.5.2.1 J

表 2.7.4.7-120. 投与 52 週時データカットオフまでの治験薬と関連ありの有害事象の基本語別の集計表（ALL_UPA_M 集団，日本人集団）：M16-045 試験

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=20) n (%)	UPA 30 mg QD (N=19) n (%)	Total (N=39) n (%)
Any adverse event	10 (50.0)	13 (68.4)	23 (59.0)
耳および迷路障害	0	1 (5.3)	1 (2.6)
突発性難聴	0	1 (5.3)	1 (2.6)
胃腸障害	0	1 (5.3)	1 (2.6)
下痢	0	1 (5.3)	1 (2.6)
悪心	0	1 (5.3)	1 (2.6)
一般・全身障害および投与部位の状態	0	1 (5.3)	1 (2.6)
顔面浮腫	0	1 (5.3)	1 (2.6)
肝胆道系障害	0	1 (5.3)	1 (2.6)
肝機能異常	0	1 (5.3)	1 (2.6)
感染症および寄生虫症	4 (20.0)	8 (42.1)	12 (30.8)
丹毒	0	1 (5.3)	1 (2.6)
毛包炎	1 (5.0)	1 (5.3)	2 (5.1)
単純ヘルペス	2 (10.0)	1 (5.3)	3 (7.7)
帯状疱疹	2 (10.0)	2 (10.5)	4 (10.3)
カポジ水痘様発疹	2 (10.0)	4 (21.1)	6 (15.4)
伝染性軟属腫	0	1 (5.3)	1 (2.6)

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

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=20) n (%)	UPA 30 mg QD (N=19) n (%)	Total (N=39) n (%)
感染症および寄生虫症 (Cont.)			
口腔ヘルペス	1 (5.0)	1 (5.3)	2 (5.1)
中耳炎	0	1 (5.3)	1 (2.6)
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 (5.0)	1 (5.3)	2 (5.1)
乳癌	1 (5.0)	0	1 (2.6)
結腸癌	1 (5.0)	0	1 (2.6)
皮膚乳頭腫	0	1 (5.3)	1 (2.6)
神経系障害	0	1 (5.3)	1 (2.6)
頭痛	0	1 (5.3)	1 (2.6)
精神障害	1 (5.0)	0	1 (2.6)
睡眠障害	1 (5.0)	0	1 (2.6)
皮膚および皮下組織障害	6 (30.0)	5 (26.3)	11 (28.2)
ざ瘡	1 (5.0)	1 (5.3)	2 (5.1)
アトピー性皮膚炎	5 (25.0)	3 (15.8)	8 (20.5)
紅斑	0	1 (5.3)	1 (2.6)
そう痒症	1 (5.0)	0	1 (2.6)

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

相互参照：M16-045 試験 W52 Japan data Table 14.3 1.8.1 J

表 2.7.4.7-121. 投与 52 週時データカットオフまでの 100 人年あたりの治験薬と関連ありの有害事象の基本語別の集計表（ALL_UPA_M 集団，日本人集団）：M16-045 試験

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=20) (PYS=32.0) Events (E/100PY)	UPA 30 mg QD (N=19) (PYS=31.0) Events (E/100PY)	Total (N=39) (PYS=63.0) Events (E/100PY)
Any adverse event	18 (56.2)	27 (87.1)	45 (71.4)
耳および迷路障害	0	1 (3.2)	1 (1.6)
突発性難聴	0	1 (3.2)	1 (1.6)
胃腸障害	0	2 (6.4)	2 (3.2)
下痢	0	1 (3.2)	1 (1.6)
悪心	0	1 (3.2)	1 (1.6)
一般・全身障害および投与部位の状態	0	1 (3.2)	1 (1.6)
顔面浮腫	0	1 (3.2)	1 (1.6)
肝胆道系障害	0	2 (6.4)	2 (3.2)
肝機能異常	0	2 (6.4)	2 (3.2)
感染症および寄生虫症	8 (25.0)	13 (41.9)	21 (33.3)
丹毒	0	1 (3.2)	1 (1.6)
毛包炎	1 (3.1)	1 (3.2)	2 (3.2)
単純ヘルペス	2 (6.2)	1 (3.2)	3 (4.8)
帯状疱疹	2 (6.2)	2 (6.4)	4 (6.3)
カポジ水痘様発疹	2 (6.2)	5 (16.1)	7 (11.1)
伝染性軟属腫	0	1 (3.2)	1 (1.6)

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.

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=20) (PYS=32.0) Events (E/100PY)	UPA 30 mg QD (N=19) (PYS=31.0) Events (E/100PY)	Total (N=39) (PYS=63.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)			
口腔ヘルペス	1 (3.1)	1 (3.2)	2 (3.2)
中耳炎	0	1 (3.2)	1 (1.6)
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）	2 (6.2)	1 (3.2)	3 (4.8)
乳癌	1 (3.1)	0	1 (1.6)
結腸癌	1 (3.1)	0	1 (1.6)
皮膚乳頭腫	0	1 (3.2)	1 (1.6)
神経系障害	0	1 (3.2)	1 (1.6)
頭痛	0	1 (3.2)	1 (1.6)
精神障害	1 (3.1)	0	1 (1.6)
睡眠障害	1 (3.1)	0	1 (1.6)
皮膚および皮下組織障害	7 (21.9)	6 (19.3)	13 (20.6)
ざ瘡	1 (3.1)	2 (6.4)	3 (4.8)
アトピー性皮膚炎	5 (15.6)	3 (9.7)	8 (12.7)
紅斑	0	1 (3.2)	1 (1.6)
そう痒症	1 (3.1)	0	1 (1.6)

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.

相互参照：M16-045 試験 W52 Japan data Table 14.3 1.8.2 J

表 2.7.4.7-122.　投与 52 週時データカットオフまでの重症度別の有害事象の基本語別の集計表（ALL_UPA_M 集団，日本人集団）：M16-045 試験

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD (N=20) n (%)	UPA 30 mg QD (N=19) n (%)	Total (N=39) n (%)
Any adverse event	19 (95.0)	18 (94.7)	37 (94.9)
Grade 1	2 (10.0)	3 (15.8)	5 (12.8)
Grade 2	15 (75.0)	13 (68.4)	28 (71.8)
Grade 3	1 (5.0)	1 (5.3)	2 (5.1)
Grade 4	1 (5.0)	1 (5.3)	2 (5.1)
血液およびリンパ系障害	1 (5.0)	1 (5.3)	2 (5.1)
Grade 1	0	1 (5.3)	1 (2.6)
Grade 2	1 (5.0)	0	1 (2.6)
リンパ節症	1 (5.0)	0	1 (2.6)
Grade 2	1 (5.0)	0	1 (2.6)
脾腫	0	1 (5.3)	1 (2.6)
Grade 1	0	1 (5.3)	1 (2.6)
耳および迷路障害	0	2 (10.5)	2 (5.1)
Grade 1	0	1 (5.3)	1 (2.6)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD (N=20) n (%)	UPA 30 mg QD (N=19) n (%)	Total (N=39) n (%)
耳および迷路障害 (Cont.)			
Grade 2	0	1 (5.3)	1 (2.6)
突発性難聴	0	1 (5.3)	1 (2.6)
Grade 2	0	1 (5.3)	1 (2.6)
鼓膜障害	0	1 (5.3)	1 (2.6)
Grade 1	0	1 (5.3)	1 (2.6)
内分泌障害	0	1 (5.3)	1 (2.6)
Grade 2	0	1 (5.3)	1 (2.6)
バセドウ病	0	1 (5.3)	1 (2.6)
Grade 2	0	1 (5.3)	1 (2.6)
眼障害	1 (5.0)	2 (10.5)	3 (7.7)
Grade 1	0	1 (5.3)	1 (2.6)
Grade 2	0	1 (5.3)	1 (2.6)
Grade 3	1 (5.0)	0	1 (2.6)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD (N=20) n (%)	UPA 30 mg QD (N=19) n (%)	Total (N=39) n (%)
眼障害 (Cont.)			
眼瞼炎	0	1 (5.3)	1 (2.6)
Grade 1	0	1 (5.3)	1 (2.6)
眼窩周囲腫脹	0	1 (5.3)	1 (2.6)
Grade 2	0	1 (5.3)	1 (2.6)
網膜剥離	1 (5.0)	0	1 (2.6)
Grade 3	1 (5.0)	0	1 (2.6)
胃腸障害	3 (15.0)	6 (31.6)	9 (23.1)
Grade 1	1 (5.0)	3 (15.8)	4 (10.3)
Grade 2	2 (10.0)	3 (15.8)	5 (12.8)
腹痛	0	2 (10.5)	2 (5.1)
Grade 1	0	2 (10.5)	2 (5.1)
上腹部痛	0	2 (10.5)	2 (5.1)
Grade 1	0	2 (10.5)	2 (5.1)
慢性胃炎	1 (5.0)	0	1 (2.6)
Grade 1	1 (5.0)	0	1 (2.6)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD (N=20) n (%)	UPA 30 mg QD (N=19) n (%)	Total (N=39) n (%)
胃腸障害 (Cont.)			
齲歯	1 (5.0)	1 (5.3)	2 (5.1)
Grade 2	1 (5.0)	1 (5.3)	2 (5.1)
下痢	1 (5.0)	1 (5.3)	2 (5.1)
Grade 2	1 (5.0)	1 (5.3)	2 (5.1)
胃食道逆流性疾患	1 (5.0)	0	1 (2.6)
Grade 1	1 (5.0)	0	1 (2.6)
痔核	0	1 (5.3)	1 (2.6)
Grade 2	0	1 (5.3)	1 (2.6)
裂孔ヘルニア	1 (5.0)	0	1 (2.6)
Grade 1	1 (5.0)	0	1 (2.6)
悪心	0	1 (5.3)	1 (2.6)
Grade 2	0	1 (5.3)	1 (2.6)
一般・全身障害および投与部位の状態	2 (10.0)	2 (10.5)	4 (10.3)
Grade 1	1 (5.0)	1 (5.3)	2 (5.1)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD (N=20) n (%)	UPA 30 mg QD (N=19) n (%)	Total (N=39) n (%)
一般・全身障害および投与部位の状態 (Cont.)			
Grade 2	1 (5.0)	1 (5.3)	2 (5.1)
顔面浮腫	1 (5.0)	1 (5.3)	2 (5.1)
Grade 2	1 (5.0)	1 (5.3)	2 (5.1)
発熱	1 (5.0)	1 (5.3)	2 (5.1)
Grade 1	1 (5.0)	1 (5.3)	2 (5.1)
肝胆道系障害	1 (5.0)	2 (10.5)	3 (7.7)
Grade 1	1 (5.0)	1 (5.3)	2 (5.1)
Grade 2	0	1 (5.3)	1 (2.6)
胆石症	0	1 (5.3)	1 (2.6)
Grade 1	0	1 (5.3)	1 (2.6)
肝機能異常	0	1 (5.3)	1 (2.6)
Grade 2	0	1 (5.3)	1 (2.6)
脂肪肝	1 (5.0)	1 (5.3)	2 (5.1)
Grade 1	1 (5.0)	1 (5.3)	2 (5.1)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD (N=20) n (%)	UPA 30 mg QD (N=19) n (%)	Total (N=39) n (%)
感染症および寄生虫症	14 (70.0)	14 (73.7)	28 (71.8)
Grade 1	3 (15.0)	3 (15.8)	6 (15.4)
Grade 2	11 (55.0)	11 (57.9)	22 (56.4)
蜂巣炎	1 (5.0)	0	1 (2.6)
Grade 2	1 (5.0)	0	1 (2.6)
膀胱炎	0	2 (10.5)	2 (5.1)
Grade 1	0	2 (10.5)	2 (5.1)
丹毒	0	1 (5.3)	1 (2.6)
Grade 2	0	1 (5.3)	1 (2.6)
毛包炎	1 (5.0)	4 (21.1)	5 (12.8)
Grade 1	0	3 (15.8)	3 (7.7)
Grade 2	1 (5.0)	1 (5.3)	2 (5.1)
胃腸炎	0	1 (5.3)	1 (2.6)
Grade 2	0	1 (5.3)	1 (2.6)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD (N=20) n (%)	UPA 30 mg QD (N=19) n (%)	Total (N=39) n (%)
感染症および寄生虫症 (Cont.)			
陰部単純ヘルペス	0	1 (5.3)	1 (2.6)
Grade 2	0	1 (5.3)	1 (2.6)
ヘルペス眼感染	0	1 (5.3)	1 (2.6)
Grade 2	0	1 (5.3)	1 (2.6)
単純ヘルペス	2 (10.0)	3 (15.8)	5 (12.8)
Grade 1	1 (5.0)	0	1 (2.6)
Grade 2	1 (5.0)	3 (15.8)	4 (10.3)
帯状疱疹	3 (15.0)	2 (10.5)	5 (12.8)
Grade 1	0	1 (5.3)	1 (2.6)
Grade 2	3 (15.0)	1 (5.3)	4 (10.3)
感染性皮膚嚢腫	0	1 (5.3)	1 (2.6)
Grade 1	0	1 (5.3)	1 (2.6)
インフルエンザ	2 (10.0)	1 (5.3)	3 (7.7)
Grade 1	0	1 (5.3)	1 (2.6)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD (N=20) n (%)	UPA 30 mg QD (N=19) n (%)	Total (N=39) n (%)
感染症および寄生虫症 (Cont.)			
インフルエンザ (Cont.)			
Grade 2	2 (10.0)	0	2 (5.1)
カポジ水痘様発疹	2 (10.0)	4 (21.1)	6 (15.4)
Grade 2	2 (10.0)	4 (21.1)	6 (15.4)
伝染性軟属腫	0	1 (5.3)	1 (2.6)
Grade 2	0	1 (5.3)	1 (2.6)
上咽頭炎	6 (30.0)	7 (36.8)	13 (33.3)
Grade 1	3 (15.0)	4 (21.1)	7 (17.9)
Grade 2	3 (15.0)	3 (15.8)	6 (15.4)
口腔ヘルペス	1 (5.0)	1 (5.3)	2 (5.1)
Grade 1	0	1 (5.3)	1 (2.6)
Grade 2	1 (5.0)	0	1 (2.6)
外耳炎	1 (5.0)	1 (5.3)	2 (5.1)
Grade 2	1 (5.0)	1 (5.3)	2 (5.1)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD (N=20) n (%)	UPA 30 mg QD (N=19) n (%)	Total (N=39) n (%)
感染症および寄生虫症 (Cont.)			
中耳炎	0	1 (5.3)	1 (2.6)
Grade 2	0	1 (5.3)	1 (2.6)
爪囲炎	1 (5.0)	1 (5.3)	2 (5.1)
Grade 2	1 (5.0)	1 (5.3)	2 (5.1)
咽頭炎	1 (5.0)	0	1 (2.6)
Grade 1	1 (5.0)	0	1 (2.6)
膿皮症	1 (5.0)	0	1 (2.6)
Grade 1	1 (5.0)	0	1 (2.6)
副鼻腔炎	0	1 (5.3)	1 (2.6)
Grade 1	0	1 (5.3)	1 (2.6)
皮膚感染	0	2 (10.5)	2 (5.1)
Grade 2	0	2 (10.5)	2 (5.1)
足部白癬	1 (5.0)	0	1 (2.6)
Grade 2	1 (5.0)	0	1 (2.6)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD (N=20) n (%)	UPA 30 mg QD (N=19) n (%)	Total (N=39) n (%)
感染症および寄生虫症 (Cont.)			
扁桃炎	0	2 (10.5)	2 (5.1)
Grade 2	0	2 (10.5)	2 (5.1)
傷害、中毒および処置合併症	4 (20.0)	3 (15.8)	7 (17.9)
Grade 1	0	1 (5.3)	1 (2.6)
Grade 2	4 (20.0)	2 (10.5)	6 (15.4)
節足動物咬傷	2 (10.0)	0	2 (5.1)
Grade 2	2 (10.0)	0	2 (5.1)
挫傷	0	1 (5.3)	1 (2.6)
Grade 2	0	1 (5.3)	1 (2.6)
足骨折	1 (5.0)	0	1 (2.6)
Grade 2	1 (5.0)	0	1 (2.6)
皮膚擦過傷	1 (5.0)	0	1 (2.6)
Grade 2	1 (5.0)	0	1 (2.6)
皮膚裂傷	0	1 (5.3)	1 (2.6)
Grade 1	0	1 (5.3)	1 (2.6)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD (N=20) n (%)	UPA 30 mg QD (N=19) n (%)	Total (N=39) n (%)
傷害、中毒および処置合併症 (Cont.)			
ストレス骨折	0	1 (5.3)	1 (2.6)
Grade 2	0	1 (5.3)	1 (2.6)
熱傷	0	1 (5.3)	1 (2.6)
Grade 1	0	1 (5.3)	1 (2.6)
臨床検査	3 (15.0)	3 (15.8)	6 (15.4)
Grade 1	1 (5.0)	1 (5.3)	2 (5.1)
Grade 2	2 (10.0)	1 (5.3)	3 (7.7)
Grade 4	0	1 (5.3)	1 (2.6)
アラニンアミノトランスフェラーゼ増加	1 (5.0)	1 (5.3)	2 (5.1)
Grade 2	1 (5.0)	1 (5.3)	2 (5.1)
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (5.3)	1 (2.6)
Grade 3	0	1 (5.3)	1 (2.6)
血中クレアチンホスホキナーゼ増加	0	3 (15.8)	3 (7.7)
Grade 1	0	1 (5.3)	1 (2.6)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD (N=20) n (%)	UPA 30 mg QD (N=19) n (%)	Total (N=39) n (%)
臨床検査 (Cont.)			
血中クレアチンホスホキナーゼ増加 (Cont.)			
Grade 2	0	1 (5.3)	1 (2.6)
Grade 4	0	1 (5.3)	1 (2.6)
血中クレアチニン増加	1 (5.0)	0	1 (2.6)
Grade 2	1 (5.0)	0	1 (2.6)
血中免疫グロブリンE増加	1 (5.0)	0	1 (2.6)
Grade 1	1 (5.0)	0	1 (2.6)
ケモカイン増加	1 (5.0)	0	1 (2.6)
Grade 1	1 (5.0)	0	1 (2.6)
筋骨格系および結合組織障害	1 (5.0)	3 (15.8)	4 (10.3)
Grade 1	0	1 (5.3)	1 (2.6)
Grade 2	1 (5.0)	2 (10.5)	3 (7.7)
背部痛	0	2 (10.5)	2 (5.1)
Grade 2	0	2 (10.5)	2 (5.1)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD (N=20) n (%)	UPA 30 mg QD (N=19) n (%)	Total (N=39) n (%)
筋骨格系および結合組織障害 (Cont.)			
足変形	1 (5.0)	0	1 (2.6)
Grade 2	1 (5.0)	0	1 (2.6)
筋骨格系胸痛	0	1 (5.3)	1 (2.6)
Grade 2	0	1 (5.3)	1 (2.6)
筋骨格痛	0	1 (5.3)	1 (2.6)
Grade 1	0	1 (5.3)	1 (2.6)
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）	2 (10.0)	2 (10.5)	4 (10.3)
Grade 1	0	1 (5.3)	1 (2.6)
Grade 2	1 (5.0)	1 (5.3)	2 (5.1)
Grade 4	1 (5.0)	0	1 (2.6)
乳癌	1 (5.0)	0	1 (2.6)
Grade 4	1 (5.0)	0	1 (2.6)
結腸癌	1 (5.0)	0	1 (2.6)
Grade 4	1 (5.0)	0	1 (2.6)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD (N=20) n (%)	UPA 30 mg QD (N=19) n (%)	Total (N=39) 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.)			
皮膚乳頭腫	1 (5.0)	2 (10.5)	3 (7.7)
Grade 1	0	1 (5.3)	1 (2.6)
Grade 2	1 (5.0)	1 (5.3)	2 (5.1)
神経系障害	0	1 (5.3)	1 (2.6)
Grade 1	0	1 (5.3)	1 (2.6)
頭痛	0	1 (5.3)	1 (2.6)
Grade 1	0	1 (5.3)	1 (2.6)
精神障害	1 (5.0)	0	1 (2.6)
Grade 2	1 (5.0)	0	1 (2.6)
睡眠障害	1 (5.0)	0	1 (2.6)
Grade 2	1 (5.0)	0	1 (2.6)
腎および尿路障害	1 (5.0)	1 (5.3)	2 (5.1)
Grade 1	1 (5.0)	1 (5.3)	2 (5.1)
腎結石症	0	1 (5.3)	1 (2.6)
Grade 1	0	1 (5.3)	1 (2.6)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD (N=20) n (%)	UPA 30 mg QD (N=19) n (%)	Total (N=39) n (%)
腎および尿路障害 (Cont.)			
尿路障害	1 (5.0)	0	1 (2.6)
Grade 1	1 (5.0)	0	1 (2.6)
生殖系および乳房障害	1 (5.0)	0	1 (2.6)
Grade 2	1 (5.0)	0	1 (2.6)
月経困難症	1 (5.0)	0	1 (2.6)
Grade 2	1 (5.0)	0	1 (2.6)
呼吸器、胸郭および縦隔障害	0	2 (10.5)	2 (5.1)
Grade 2	0	2 (10.5)	2 (5.1)
喘息	0	1 (5.3)	1 (2.6)
Grade 2	0	1 (5.3)	1 (2.6)
アレルギー性鼻炎	0	1 (5.3)	1 (2.6)
Grade 2	0	1 (5.3)	1 (2.6)
上気道の炎症	0	1 (5.3)	1 (2.6)
Grade 2	0	1 (5.3)	1 (2.6)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD (N=20) n (%)	UPA 30 mg QD (N=19) n (%)	Total (N=39) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)			
声帯肥厚	0	1 (5.3)	1 (2.6)
Grade 2	0	1 (5.3)	1 (2.6)
皮膚および皮下組織障害	12 (60.0)	11 (57.9)	23 (59.0)
Grade 1	0	2 (10.5)	2 (5.1)
Grade 2	12 (60.0)	8 (42.1)	20 (51.3)
Grade 3	0	1 (5.3)	1 (2.6)
ざ瘡	2 (10.0)	5 (26.3)	7 (17.9)
Grade 1	0	1 (5.3)	1 (2.6)
Grade 2	2 (10.0)	4 (21.1)	6 (15.4)
皮膚嚢腫	0	1 (5.3)	1 (2.6)
Grade 2	0	1 (5.3)	1 (2.6)
ざ瘡様皮膚炎	0	2 (10.5)	2 (5.1)
Grade 1	0	1 (5.3)	1 (2.6)
Grade 2	0	1 (5.3)	1 (2.6)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD (N=20) n (%)	UPA 30 mg QD (N=19) n (%)	Total (N=39) n (%)
皮膚および皮下組織障害 (Cont.)			
アトピー性皮膚炎	11 (55.0)	6 (31.6)	17 (43.6)
Grade 1	0	1 (5.3)	1 (2.6)
Grade 2	11 (55.0)	5 (26.3)	16 (41.0)
接触皮膚炎	1 (5.0)	2 (10.5)	3 (7.7)
Grade 2	1 (5.0)	1 (5.3)	2 (5.1)
Grade 3	0	1 (5.3)	1 (2.6)
湿疹	0	1 (5.3)	1 (2.6)
Grade 2	0	1 (5.3)	1 (2.6)
紅斑	0	1 (5.3)	1 (2.6)
Grade 2	0	1 (5.3)	1 (2.6)
そう痒症	2 (10.0)	0	2 (5.1)
Grade 2	2 (10.0)	0	2 (5.1)
黄色板腫	1 (5.0)	0	1 (2.6)
Grade 2	1 (5.0)	0	1 (2.6)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

相互参照：M16-045 試験 W52 Japan data Table 14.3 1.9.1 J

表 2.7.4.7-123. 投与 52 週時データカットオフまでの 100 人年あたりの重症度別の有害事象の基本語別の集計表（ALL_UPA_M 集団，日本人集団）：M16-045 試験

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD (N=20) (PYS=32.0) Events (E/100PY)	UPA 30 mg QD (N=19) (PYS=31.0) Events (E/100PY)	Total (N=39) (PYS=63.0) Events (E/100PY)
Any adverse event	66 (206.1)	113 (364.4)	179 (284.0)
Grade 1	15 (46.8)	39 (125.8)	54 (85.7)
Grade 2	48 (149.9)	71 (228.9)	119 (188.8)
Grade 3	1 (3.1)	2 (6.4)	3 (4.8)
Grade 4	2 (6.2)	1 (3.2)	3 (4.8)
血液およびリンパ系障害	1 (3.1)	1 (3.2)	2 (3.2)
Grade 1	0	1 (3.2)	1 (1.6)
Grade 2	1 (3.1)	0	1 (1.6)
リンパ節症	1 (3.1)	0	1 (1.6)
Grade 2	1 (3.1)	0	1 (1.6)
脾腫	0	1 (3.2)	1 (1.6)
Grade 1	0	1 (3.2)	1 (1.6)
耳および迷路障害	0	2 (6.4)	2 (3.2)
Grade 1	0	1 (3.2)	1 (1.6)
Grade 2	0	1 (3.2)	1 (1.6)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject.
E/100PY = Events per 100 patient-years.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD (N=20) (PYS=32.0) Events (E/100PY)	UPA 30 mg QD (N=19) (PYS=31.0) Events (E/100PY)	Total (N=39) (PYS=63.0) Events (E/100PY)
耳および迷路障害 (Cont.)			
突発性難聴	0	1 (3.2)	1 (1.6)
Grade 2	0	1 (3.2)	1 (1.6)
鼓膜障害	0	1 (3.2)	1 (1.6)
Grade 1	0	1 (3.2)	1 (1.6)
内分泌障害	0	1 (3.2)	1 (1.6)
Grade 2	0	1 (3.2)	1 (1.6)
バセドウ病	0	1 (3.2)	1 (1.6)
Grade 2	0	1 (3.2)	1 (1.6)
眼障害	1 (3.1)	2 (6.4)	3 (4.8)
Grade 1	0	1 (3.2)	1 (1.6)
Grade 2	0	1 (3.2)	1 (1.6)
Grade 3	1 (3.1)	0	1 (1.6)
眼瞼炎	0	1 (3.2)	1 (1.6)
Grade 1	0	1 (3.2)	1 (1.6)
眼窩周囲腫脹	0	1 (3.2)	1 (1.6)
Grade 2	0	1 (3.2)	1 (1.6)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject.
E/100PY = Events per 100 patient-years.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD (N=20) (PYS=32.0) Events (E/100PY)	UPA 30 mg QD (N=19) (PYS=31.0) Events (E/100PY)	Total (N=39) (PYS=63.0) Events (E/100PY)
眼障害 (Cont.)			
網膜剥離	1 (3.1)	0	1 (1.6)
Grade 3	1 (3.1)	0	1 (1.6)
胃腸障害	5 (15.6)	9 (29.0)	14 (22.2)
Grade 1	3 (9.4)	4 (12.9)	7 (11.1)
Grade 2	2 (6.2)	5 (16.1)	7 (11.1)
腹痛	0	2 (6.4)	2 (3.2)
Grade 1	0	2 (6.4)	2 (3.2)
上腹部痛	0	2 (6.4)	2 (3.2)
Grade 1	0	2 (6.4)	2 (3.2)
慢性胃炎	1 (3.1)	0	1 (1.6)
Grade 1	1 (3.1)	0	1 (1.6)
齲歯	1 (3.1)	1 (3.2)	2 (3.2)
Grade 2	1 (3.1)	1 (3.2)	2 (3.2)
下痢	1 (3.1)	1 (3.2)	2 (3.2)
Grade 2	1 (3.1)	1 (3.2)	2 (3.2)
胃食道逆流性疾患	1 (3.1)	0	1 (1.6)
Grade 1	1 (3.1)	0	1 (1.6)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject.
E/100PY = Events per 100 patient-years.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD (N=20) (PYS=32.0) Events (E/100PY)	UPA 30 mg QD (N=19) (PYS=31.0) Events (E/100PY)	Total (N=39) (PYS=63.0) Events (E/100PY)
胃腸障害 (Cont.)			
痔核	0	2 (6.4)	2 (3.2)
Grade 2	0	2 (6.4)	2 (3.2)
裂孔ヘルニア	1 (3.1)	0	1 (1.6)
Grade 1	1 (3.1)	0	1 (1.6)
悪心	0	1 (3.2)	1 (1.6)
Grade 2	0	1 (3.2)	1 (1.6)
一般・全身障害および投与部位の状態	2 (6.2)	2 (6.4)	4 (6.3)
Grade 1	1 (3.1)	1 (3.2)	2 (3.2)
Grade 2	1 (3.1)	1 (3.2)	2 (3.2)
顔面浮腫	1 (3.1)	1 (3.2)	2 (3.2)
Grade 2	1 (3.1)	1 (3.2)	2 (3.2)
発熱	1 (3.1)	1 (3.2)	2 (3.2)
Grade 1	1 (3.1)	1 (3.2)	2 (3.2)
肝胆道系障害	1 (3.1)	4 (12.9)	5 (7.9)
Grade 1	1 (3.1)	3 (9.7)	4 (6.3)
Grade 2	0	1 (3.2)	1 (1.6)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject.
E/100PY = Events per 100 patient-years.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD (N=20) (PYS=32.0) Events (E/100PY)	UPA 30 mg QD (N=19) (PYS=31.0) Events (E/100PY)	Total (N=39) (PYS=63.0) Events (E/100PY)
肝胆道系障害 (Cont.)			
胆石症	0	1 (3.2)	1 (1.6)
Grade 1	0	1 (3.2)	1 (1.6)
肝機能異常	0	2 (6.4)	2 (3.2)
Grade 1	0	1 (3.2)	1 (1.6)
Grade 2	0	1 (3.2)	1 (1.6)
脂肪肝	1 (3.1)	1 (3.2)	2 (3.2)
Grade 1	1 (3.1)	1 (3.2)	2 (3.2)
感染症および寄生虫症	24 (74.9)	50 (161.2)	74 (117.4)
Grade 1	7 (21.9)	18 (58.0)	25 (39.7)
Grade 2	17 (53.1)	32 (103.2)	49 (77.7)
蜂巣炎	1 (3.1)	0	1 (1.6)
Grade 2	1 (3.1)	0	1 (1.6)
膀胱炎	0	2 (6.4)	2 (3.2)
Grade 1	0	2 (6.4)	2 (3.2)
丹毒	0	1 (3.2)	1 (1.6)
Grade 2	0	1 (3.2)	1 (1.6)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject.
E/100PY = Events per 100 patient-years.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD (N=20) (PYS=32.0) Events (E/100PY)	UPA 30 mg QD (N=19) (PYS=31.0) Events (E/100PY)	Total (N=39) (PYS=63.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)			
毛包炎	1 (3.1)	4 (12.9)	5 (7.9)
Grade 1	0	3 (9.7)	3 (4.8)
Grade 2	1 (3.1)	1 (3.2)	2 (3.2)
胃腸炎	0	1 (3.2)	1 (1.6)
Grade 2	0	1 (3.2)	1 (1.6)
陰部単純ヘルペス	0	2 (6.4)	2 (3.2)
Grade 2	0	2 (6.4)	2 (3.2)
ヘルペス眼感染	0	4 (12.9)	4 (6.3)
Grade 2	0	4 (12.9)	4 (6.3)
単純ヘルペス	2 (6.2)	5 (16.1)	7 (11.1)
Grade 1	1 (3.1)	1 (3.2)	2 (3.2)
Grade 2	1 (3.1)	4 (12.9)	5 (7.9)
帯状疱疹	3 (9.4)	2 (6.4)	5 (7.9)
Grade 1	0	1 (3.2)	1 (1.6)
Grade 2	3 (9.4)	1 (3.2)	4 (6.3)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject.
E/100PY = Events per 100 patient-years.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD (N=20) (PYS=32.0) Events (E/100PY)	UPA 30 mg QD (N=19) (PYS=31.0) Events (E/100PY)	Total (N=39) (PYS=63.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)			
感染性皮膚嚢腫	0	1 (3.2)	1 (1.6)
Grade 1	0	1 (3.2)	1 (1.6)
インフルエンザ	2 (6.2)	1 (3.2)	3 (4.8)
Grade 1	0	1 (3.2)	1 (1.6)
Grade 2	2 (6.2)	0	2 (3.2)
カポジ水痘様発疹	2 (6.2)	5 (16.1)	7 (11.1)
Grade 2	2 (6.2)	5 (16.1)	7 (11.1)
伝染性軟属腫	0	1 (3.2)	1 (1.6)
Grade 2	0	1 (3.2)	1 (1.6)
上咽頭炎	6 (18.7)	9 (29.0)	15 (23.8)
Grade 1	3 (9.4)	5 (16.1)	8 (12.7)
Grade 2	3 (9.4)	4 (12.9)	7 (11.1)
口腔ヘルペス	1 (3.1)	1 (3.2)	2 (3.2)
Grade 1	0	1 (3.2)	1 (1.6)
Grade 2	1 (3.1)	0	1 (1.6)
外耳炎	1 (3.1)	2 (6.4)	3 (4.8)
Grade 1	0	1 (3.2)	1 (1.6)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject.
E/100PY = Events per 100 patient-years.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD (N=20) (PYS=32.0) Events (E/100PY)	UPA 30 mg QD (N=19) (PYS=31.0) Events (E/100PY)	Total (N=39) (PYS=63.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)			
外耳炎 (Cont.)			
Grade 2	1 (3.1)	1 (3.2)	2 (3.2)
中耳炎	0	1 (3.2)	1 (1.6)
Grade 2	0	1 (3.2)	1 (1.6)
爪囲炎	1 (3.1)	1 (3.2)	2 (3.2)
Grade 2	1 (3.1)	1 (3.2)	2 (3.2)
咽頭炎	2 (6.2)	0	2 (3.2)
Grade 1	2 (6.2)	0	2 (3.2)
膿皮症	1 (3.1)	0	1 (1.6)
Grade 1	1 (3.1)	0	1 (1.6)
副鼻腔炎	0	1 (3.2)	1 (1.6)
Grade 1	0	1 (3.2)	1 (1.6)
皮膚感染	0	2 (6.4)	2 (3.2)
Grade 2	0	2 (6.4)	2 (3.2)
足部白癬	1 (3.1)	0	1 (1.6)
Grade 2	1 (3.1)	0	1 (1.6)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject.
E/100PY = Events per 100 patient-years.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD (N=20) (PYS=32.0) Events (E/100PY)	UPA 30 mg QD (N=19) (PYS=31.0) Events (E/100PY)	Total (N=39) (PYS=63.0) Events (E/100PY)
感染症および寄生虫症 (Cont.)			
扁桃炎	0	4 (12.9)	4 (6.3)
Grade 1	0	1 (3.2)	1 (1.6)
Grade 2	0	3 (9.7)	3 (4.8)
傷害、中毒および処置合併症	4 (12.5)	5 (16.1)	9 (14.3)
Grade 1	0	2 (6.4)	2 (3.2)
Grade 2	4 (12.5)	3 (9.7)	7 (11.1)
節足動物咬傷	2 (6.2)	0	2 (3.2)
Grade 2	2 (6.2)	0	2 (3.2)
挫傷	0	1 (3.2)	1 (1.6)
Grade 2	0	1 (3.2)	1 (1.6)
足骨折	1 (3.1)	0	1 (1.6)
Grade 2	1 (3.1)	0	1 (1.6)
皮膚擦過傷	1 (3.1)	0	1 (1.6)
Grade 2	1 (3.1)	0	1 (1.6)
皮膚裂傷	0	1 (3.2)	1 (1.6)
Grade 1	0	1 (3.2)	1 (1.6)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject.
E/100PY = Events per 100 patient-years.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD (N=20) (PYS=32.0) Events (E/100PY)	UPA 30 mg QD (N=19) (PYS=31.0) Events (E/100PY)	Total (N=39) (PYS=63.0) Events (E/100PY)
傷害、中毒および処置合併症 (Cont.)			
ストレス骨折	0	2 (6.4)	2 (3.2)
Grade 2	0	2 (6.4)	2 (3.2)
熱傷	0	1 (3.2)	1 (1.6)
Grade 1	0	1 (3.2)	1 (1.6)
臨床検査	4 (12.5)	5 (16.1)	9 (14.3)
Grade 1	2 (6.2)	1 (3.2)	3 (4.8)
Grade 2	2 (6.2)	2 (6.4)	4 (6.3)
Grade 3	0	1 (3.2)	1 (1.6)
Grade 4	0	1 (3.2)	1 (1.6)
アラニンアミノトランスフェラーゼ増加	1 (3.1)	1 (3.2)	2 (3.2)
Grade 2	1 (3.1)	1 (3.2)	2 (3.2)
アスパラギン酸アミノトランスフェラーゼ増加	0	1 (3.2)	1 (1.6)
Grade 3	0	1 (3.2)	1 (1.6)
血中クレアチンホスホキナーゼ増加	0	3 (9.7)	3 (4.8)
Grade 1	0	1 (3.2)	1 (1.6)
Grade 2	0	1 (3.2)	1 (1.6)
Grade 4	0	1 (3.2)	1 (1.6)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject.
E/100PY = Events per 100 patient-years.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD (N=20) (PYS=32.0) Events (E/100PY)	UPA 30 mg QD (N=19) (PYS=31.0) Events (E/100PY)	Total (N=39) (PYS=63.0) Events (E/100PY)
臨床検査 (Cont.)			
血中クレアチニン増加	1 (3.1)	0	1 (1.6)
Grade 2	1 (3.1)	0	1 (1.6)
血中免疫グロブリンE増加	1 (3.1)	0	1 (1.6)
Grade 1	1 (3.1)	0	1 (1.6)
ケモカイン増加	1 (3.1)	0	1 (1.6)
Grade 1	1 (3.1)	0	1 (1.6)
筋骨格系および結合組織障害	1 (3.1)	4 (12.9)	5 (7.9)
Grade 1	0	1 (3.2)	1 (1.6)
Grade 2	1 (3.1)	3 (9.7)	4 (6.3)
背部痛	0	2 (6.4)	2 (3.2)
Grade 2	0	2 (6.4)	2 (3.2)
足変形	1 (3.1)	0	1 (1.6)
Grade 2	1 (3.1)	0	1 (1.6)
筋骨格系胸痛	0	1 (3.2)	1 (1.6)
Grade 2	0	1 (3.2)	1 (1.6)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject.
E/100PY = Events per 100 patient-years.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD (N=20) (PYS=32.0) Events (E/100PY)	UPA 30 mg QD (N=19) (PYS=31.0) Events (E/100PY)	Total (N=39) (PYS=63.0) Events (E/100PY)
筋骨格系および結合組織障害 (Cont.)			
筋骨格痛	0	1 (3.2)	1 (1.6)
Grade 1	0	1 (3.2)	1 (1.6)
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）	3 (9.4)	2 (6.4)	5 (7.9)
Grade 1	0	1 (3.2)	1 (1.6)
Grade 2	1 (3.1)	1 (3.2)	2 (3.2)
Grade 4	2 (6.2)	0	2 (3.2)
乳癌	1 (3.1)	0	1 (1.6)
Grade 4	1 (3.1)	0	1 (1.6)
結腸癌	1 (3.1)	0	1 (1.6)
Grade 4	1 (3.1)	0	1 (1.6)
皮膚乳頭腫	1 (3.1)	2 (6.4)	3 (4.8)
Grade 1	0	1 (3.2)	1 (1.6)
Grade 2	1 (3.1)	1 (3.2)	2 (3.2)
神経系障害	0	1 (3.2)	1 (1.6)
Grade 1	0	1 (3.2)	1 (1.6)
頭痛	0	1 (3.2)	1 (1.6)
Grade 1	0	1 (3.2)	1 (1.6)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject.
E/100PY = Events per 100 patient-years.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD (N=20) (PYS=32.0) Events (E/100PY)	UPA 30 mg QD (N=19) (PYS=31.0) Events (E/100PY)	Total (N=39) (PYS=63.0) Events (E/100PY)
精神障害	1 (3.1)	0	1 (1.6)
Grade 2	1 (3.1)	0	1 (1.6)
睡眠障害	1 (3.1)	0	1 (1.6)
Grade 2	1 (3.1)	0	1 (1.6)
腎および尿路障害	1 (3.1)	1 (3.2)	2 (3.2)
Grade 1	1 (3.1)	1 (3.2)	2 (3.2)
腎結石症	0	1 (3.2)	1 (1.6)
Grade 1	0	1 (3.2)	1 (1.6)
尿路障害	1 (3.1)	0	1 (1.6)
Grade 1	1 (3.1)	0	1 (1.6)
生殖系および乳房障害	1 (3.1)	0	1 (1.6)
Grade 2	1 (3.1)	0	1 (1.6)
月経困難症	1 (3.1)	0	1 (1.6)
Grade 2	1 (3.1)	0	1 (1.6)
呼吸器、胸郭および縦隔障害	0	5 (16.1)	5 (7.9)
Grade 2	0	5 (16.1)	5 (7.9)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject.
E/100PY = Events per 100 patient-years.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD (N=20) (PYS=32.0) Events (E/100PY)	UPA 30 mg QD (N=19) (PYS=31.0) Events (E/100PY)	Total (N=39) (PYS=63.0) Events (E/100PY)
呼吸器、胸郭および縦隔障害 (Cont.)			
喘息	0	2 (6.4)	2 (3.2)
Grade 2	0	2 (6.4)	2 (3.2)
アレルギー性鼻炎	0	1 (3.2)	1 (1.6)
Grade 2	0	1 (3.2)	1 (1.6)
上気道の炎症	0	1 (3.2)	1 (1.6)
Grade 2	0	1 (3.2)	1 (1.6)
声帯肥厚	0	1 (3.2)	1 (1.6)
Grade 2	0	1 (3.2)	1 (1.6)
皮膚および皮下組織障害	17 (53.1)	19 (61.3)	36 (57.1)
Grade 1	0	3 (9.7)	3 (4.8)
Grade 2	17 (53.1)	15 (48.4)	32 (50.8)
Grade 3	0	1 (3.2)	1 (1.6)
ざ瘡	2 (6.2)	6 (19.3)	8 (12.7)
Grade 1	0	1 (3.2)	1 (1.6)
Grade 2	2 (6.2)	5 (16.1)	7 (11.1)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject.
E/100PY = Events per 100 patient-years.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD (N=20) (PYS=32.0) Events (E/100PY)	UPA 30 mg QD (N=19) (PYS=31.0) Events (E/100PY)	Total (N=39) (PYS=63.0) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)			
皮膚嚢腫	0	1 (3.2)	1 (1.6)
Grade 2	0	1 (3.2)	1 (1.6)
ざ瘡様皮膚炎	0	2 (6.4)	2 (3.2)
Grade 1	0	1 (3.2)	1 (1.6)
Grade 2	0	1 (3.2)	1 (1.6)
アトピー性皮膚炎	11 (34.3)	6 (19.3)	17 (27.0)
Grade 1	0	1 (3.2)	1 (1.6)
Grade 2	11 (34.3)	5 (16.1)	16 (25.4)
接触皮膚炎	1 (3.1)	2 (6.4)	3 (4.8)
Grade 2	1 (3.1)	1 (3.2)	2 (3.2)
Grade 3	0	1 (3.2)	1 (1.6)
湿疹	0	1 (3.2)	1 (1.6)
Grade 2	0	1 (3.2)	1 (1.6)
紅斑	0	1 (3.2)	1 (1.6)
Grade 2	0	1 (3.2)	1 (1.6)
そう痒症	2 (6.2)	0	2 (3.2)
Grade 2	2 (6.2)	0	2 (3.2)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject.
E/100PY = Events per 100 patient-years.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD (N=20) (PYS=32.0) Events (E/100PY)	UPA 30 mg QD (N=19) (PYS=31.0) Events (E/100PY)	Total (N=39) (PYS=63.0) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)			
黄色板腫	1 (3.1)	0	1 (1.6)
Grade 2	1 (3.1)	0	1 (1.6)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject.
E/100PY = Events per 100 patient-years.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

相互参照：M16-045 試験 W52 Japan data Table 14.3 1.9.2 J

表 2.7.4.7-124.　投与 16 週時までの治験薬の投与中止に至った有害事象の集計表（Safety_DB_M 集団，日本人集団）：M16-045 試験

MedDRA 22.1 System Organ Class Preferred Term	Placebo (N=14) n (%)	Active UPA 15 mg QD (N=15) n (%)	Active UPA 30 mg QD (N=16) n (%)	Total (N=31) n (%)
Any adverse event	4 (28.6)	0	1 (6.3)	1 (3.2)
一般・全身障害および投与部位の状態	0	0	1 (6.3)	1 (3.2)
顔面浮腫	0	0	1 (6.3)	1 (3.2)
皮膚および皮下組織障害	4 (28.6)	0	1 (6.3)	1 (3.2)
アトピー性皮膚炎	3 (21.4)	0	0	0
紅斑	1 (7.1)	0	1 (6.3)	1 (3.2)

Note: Treatment-emergent adverse events in DB Period are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or no more than 30 days after the last dose of study drug in DB Period, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.

相互参照：M16-045 試験 W16 Japan data Table 14.3　2.3.1_J

表 2.7.4.7-125.　投与 52 週時データカットオフまでの治験薬の投与中止に至った有害事象の集計表（ALL_UPA_M 集団，日本人集団）：M16-045 試験

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=20) n (%)	UPA 30 mg QD (N=19) n (%)	Total (N=39) n (%)
Any adverse event	3 (15.0)	3 (15.8)	6 (15.4)
一般・全身障害および投与部位の状態	0	1 (5.3)	1 (2.6)
顔面浮腫	0	1 (5.3)	1 (2.6)
肝胆道系障害	0	1 (5.3)	1 (2.6)
肝機能異常	0	1 (5.3)	1 (2.6)
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 (5.0)	0	1 (2.6)
乳癌	1 (5.0)	0	1 (2.6)
精神障害	1 (5.0)	0	1 (2.6)
睡眠障害	1 (5.0)	0	1 (2.6)
皮膚および皮下組織障害	2 (10.0)	2 (10.5)	4 (10.3)
アトピー性皮膚炎	1 (5.0)	1 (5.3)	2 (5.1)
紅斑	0	1 (5.3)	1 (2.6)
そう痒症	1 (5.0)	0	1 (2.6)

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

相互参照：M16-045 試験 W52 Japan data Table 14.3　2.3.1_J

表 2.7.4.7-126. 投与 52 週時データカットオフまでの 100 人年あたりの治験薬の投与中止に至った有害事象の集計表（ALL_UPA_M 集団，日本人集団）：M16-045 試験

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD (N=20) (PYS=32.0) Events (E/100PY)	UPA 30 mg QD (N=19) (PYS=31.0) Events (E/100PY)	Total (N=39) (PYS=63.0) Events (E/100PY)
Any adverse event	4 (12.5)	4 (12.9)	8 (12.7)
一般・全身障害および投与部位の状態	0	1 (3.2)	1 (1.6)
顔面浮腫	0	1 (3.2)	1 (1.6)
肝胆道系障害	0	1 (3.2)	1 (1.6)
肝機能異常	0	1 (3.2)	1 (1.6)
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 (3.1)	0	1 (1.6)
乳癌	1 (3.1)	0	1 (1.6)
精神障害	1 (3.1)	0	1 (1.6)
睡眠障害	1 (3.1)	0	1 (1.6)
皮膚および皮下組織障害	2 (6.2)	2 (6.4)	4 (6.3)
アトピー性皮膚炎	1 (3.1)	1 (3.2)	2 (3.2)
紅斑	0	1 (3.2)	1 (1.6)
そう痒症	1 (3.1)	0	1 (1.6)

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.

相互参照：M16-045 試験 W52 Japan data Table 14.3 2.3.2 J

表 2.7.4.7-127.　投与 16 週時までの曝露状況（Safety_DB_M 集団，日本人集団）：M16-047 試験

	Placebo + TCS (N=18)	Active: UPA 15 mg QD + TCS (N=16)	Active: UPA 30 mg QD + TCS (N=17)	Total (N=33)
Duration (Days)				
n	18	16	17	33
Mean (SD)	111.8 (1.22)	111.9 (1.20)	111.5 (1.23)	111.7 (1.22)
Median	112.0	112.0	112.0	112.0
Min, Max	109, 115	110, 115	109, 113	109, 115

Note: For subjects who did not continue into BE Period, duration is defined as date of last dose of study drug in DB Period - date of first dose of study drug in DB Period + 1; For subjects who continued into BE Period, duration is defined as the minimum of (date of first dose of study drug in BE Period - date of first dose of study drug in DB Period) and (date of last dose of study drug in DB Period - date of first dose of study drug in DB Period + 1).

相互参照：M16-047 試験 W16 Japan data Table 14.1　8.1.1_J

表 2.7.4.7-128.　投与 52 週時データカットオフまでの曝露状況（ALL_UPA_M 集団，日本人集団）：M16-047 試験

	UPA 15 mg QD + TCS (N=24)	UPA 30 mg QD + TCS (N=26)	Total (N=50)
Duration (days)			
n	24	26	50
Mean (SD)	643.1 (112.61)	667.8 (76.05)	655.9 (95.18)
Median	669.0	666.5	668.0
Min, Max	293, 767	504, 787	293, 787
Duration (weeks)			
>= 4 weeks	24 (100)	26 (100)	50 (100)
>= 12 weeks	24 (100)	26 (100)	50 (100)
>= 24 weeks	24 (100)	26 (100)	50 (100)
>= 36 weeks	24 (100)	26 (100)	50 (100)
>= 48 weeks	23 (95.8)	26 (100)	49 (98.0)
>= 52 weeks	23 (95.8)	26 (100)	49 (98.0)
>= 72 weeks	22 (91.7)	26 (100)	48 (96.0)
>= 104 weeks	5 (20.8)	8 (30.8)	13 (26.0)
>= 130 weeks	0	0	0

Note: Duration of treatment = The date of last dose of upadacitinib - the date of first dose of upadacitinib + 1.

相互参照：M16-047 試験 W52 Japan data Table 14.1　7.2.1_J

表 2.7.4.7-129.　投与 16 週時までの全有害事象の集計表（Safety_DB_M 集団，日本人集団）：M16-047 試験

MedDRA 22.1 System Organ Class Preferred Term	Placebo + TCS (N=18) n (%)	Active UPA 15 mg QD + TCS (N=16) n (%)	Active UPA 30 mg QD + TCS (N=17) n (%)	Total (N=33) n (%)
Any adverse event	10 (55.6)	10 (62.5)	8 (47.1)	18 (54.5)
血液およびリンパ系障害	1 (5.6)	0	0	0
貧血	1 (5.6)	0	0	0
眼障害	2 (11.1)	0	0	0
網膜動脈閉塞	1 (5.6)	0	0	0
裂孔原性網膜剥離	1 (5.6)	0	0	0
胃腸障害	1 (5.6)	3 (18.8)	0	3 (9.1)
腹部膨満	0	1 (6.3)	0	1 (3.0)
齲歯	0	1 (6.3)	0	1 (3.0)
腸炎	1 (5.6)	0	0	0
胃炎	1 (5.6)	0	0	0
胃腸粘膜障害	0	1 (6.3)	0	1 (3.0)
一般・全身障害および投与部位の状態	0	1 (6.3)	2 (11.8)	3 (9.1)
胸痛	0	1 (6.3)	0	1 (3.0)
発熱	0	0	2 (11.8)	2 (6.1)
免疫系障害	1 (5.6)	0	0	0
季節性アレルギー	1 (5.6)	0	0	0

Note: Treatment-emergent adverse events in DB Period are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or no more than 30 days after the last dose of study drug in DB Period, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.

MedDRA 22.1 System Organ Class Preferred Term	Placebo + TCS (N=18) n (%)	Active UPA 15 mg QD + TCS (N=16) n (%)	Active UPA 30 mg QD + TCS (N=17) n (%)	Total (N=33) n (%)
感染症および寄生虫症	7 (38.9)	9 (56.3)	6 (35.3)	15 (45.5)
蜂巣炎	1 (5.6)	0	0	0
心内膜炎	1 (5.6)	0	0	0
丹毒	2 (11.1)	0	0	0
毛包炎	0	1 (6.3)	1 (5.9)	2 (6.1)
麦粒腫	0	0	1 (5.9)	1 (3.0)
インフルエンザ	1 (5.6)	4 (25.0)	2 (11.8)	6 (18.2)
カポジ水痘様発疹	0	1 (6.3)	0	1 (3.0)
鼻ヘルペス	0	0	1 (5.9)	1 (3.0)
上咽頭炎	0	6 (37.5)	2 (11.8)	8 (24.2)
口腔ヘルペス	0	0	1 (5.9)	1 (3.0)
須毛瘡	1 (5.6)	0	0	0
癜風	1 (5.6)	0	0	0
上気道感染	2 (11.1)	0	0	0
傷害、中毒および処置合併症	0	0	1 (5.9)	1 (3.0)
創傷	0	0	1 (5.9)	1 (3.0)

Note: Treatment-emergent adverse events in DB Period are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or no more than 30 days after the last dose of study drug in DB Period, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.

MedDRA 22.1 System Organ Class Preferred Term	Placebo + TCS (N=18) n (%)	Active UPA 15 mg QD + TCS (N=16) n (%)	Active UPA 30 mg QD + TCS (N=17) n (%)	Total (N=33) n (%)
臨床検査	1 (5.6)	1 (6.3)	1 (5.9)	2 (6.1)
アラニンアミノトランスフェラーゼ増加	0	0	1 (5.9)	1 (3.0)
血中クレアチンホスホキナーゼ増加	1 (5.6)	0	0	0
血小板数減少	1 (5.6)	0	0	0
血小板数増加	1 (5.6)	0	0	0
体重増加	0	1 (6.3)	0	1 (3.0)
神経系障害	1 (5.6)	0	1 (5.9)	1 (3.0)
脳梗塞	1 (5.6)	0	0	0
傾眠	0	0	1 (5.9)	1 (3.0)
呼吸器、胸郭および縦隔障害	0	2 (12.5)	1 (5.9)	3 (9.1)
喘息	0	1 (6.3)	0	1 (3.0)
咳嗽	0	1 (6.3)	0	1 (3.0)
鼻出血	0	0	1 (5.9)	1 (3.0)
皮膚および皮下組織障害	3 (16.7)	0	3 (17.6)	3 (9.1)
ざ瘡	2 (11.1)	0	3 (17.6)	3 (9.1)
脱毛症	1 (5.6)	0	0	0

Note: Treatment-emergent adverse events in DB Period are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or no more than 30 days after the last dose of study drug in DB Period, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.

相互参照：M16-047 試験 W16 Japan data Table 14.3 1.6.1.1 J

表 2.7.4.7-130.　投与 16 週時までの治験薬と関連ありの有害事象の基本語別の集計表（Safety_DB_M 集団，日本人集団）：M16-047 試験

MedDRA 22.1 System Organ Class Preferred Term	Placebo + TCS (N=18) n (%)	Active UPA 15 mg QD + TCS (N=16) n (%)	Active UPA 30 mg QD + TCS (N=17) n (%)	Total (N=33) n (%)
Any adverse event	1 (5.6)	3 (18.8)	5 (29.4)	8 (24.2)
胃腸障害	0	1 (6.3)	0	1 (3.0)
腹部膨満	0	1 (6.3)	0	1 (3.0)
一般・全身障害および投与部位の状態	0	0	1 (5.9)	1 (3.0)
発熱	0	0	1 (5.9)	1 (3.0)
感染症および寄生虫症	1 (5.6)	2 (12.5)	2 (11.8)	4 (12.1)
麦粒腫	0	0	1 (5.9)	1 (3.0)
インフルエンザ	0	0	1 (5.9)	1 (3.0)
カポジ水痘様発疹	0	1 (6.3)	0	1 (3.0)
上咽頭炎	0	1 (6.3)	0	1 (3.0)
癜風	1 (5.6)	0	0	0
臨床検査	0	0	1 (5.9)	1 (3.0)
アラニンアミノトランスフェラーゼ増加	0	0	1 (5.9)	1 (3.0)
神経系障害	0	0	1 (5.9)	1 (3.0)
傾眠	0	0	1 (5.9)	1 (3.0)
皮膚および皮下組織障害	0	0	1 (5.9)	1 (3.0)
ざ瘡	0	0	1 (5.9)	1 (3.0)

Note: Treatment-emergent adverse events in DB Period are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or no more than 30 days after the last dose of study drug in DB Period, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.

相互参照：M16-047 試験 W16 Japan data Table 14.3　1.10.1 J

表 2.7.4.7-131. 投与 16 週時までの重症度別の有害事象の基本語別の集計表（Safety_DB_M 集団，日本人集団）：M16-047 試験

MedDRA 22.1 System Organ Class Preferred Term Toxicity	Placebo + TCS (N=18) n (%)	Active UPA 15 mg QD + TCS (N=16) n (%)	Active UPA 30 mg QD + TCS (N=17) n (%)	Total (N=33) n (%)
Any adverse event	10 (55.6)	10 (62.5)	8 (47.1)	18 (54.5)
Grade 1	2 (11.1)	3 (18.8)	5 (29.4)	8 (24.2)
Grade 2	7 (38.9)	7 (43.8)	3 (17.6)	10 (30.3)
Grade 3	1 (5.6)	0	0	0
血液およびリンパ系障害	1 (5.6)	0	0	0
Grade 1	1 (5.6)	0	0	0
貧血	1 (5.6)	0	0	0
Grade 1	1 (5.6)	0	0	0
眼障害	2 (11.1)	0	0	0
Grade 1	1 (5.6)	0	0	0
Grade 3	1 (5.6)	0	0	0
網膜動脈閉塞	1 (5.6)	0	0	0
Grade 1	1 (5.6)	0	0	0

Note: Treatment-emergent adverse events in DB Period are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or no more than 30 days after the last dose of study drug in DB Period, whichever occurs firstly.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	Placebo + TCS (N=18) n (%)	Active UPA 15 mg QD + TCS (N=16) n (%)	Active UPA 30 mg QD + TCS (N=17) n (%)	Total (N=33) n (%)
眼障害 (Cont.)				
裂孔原性網膜剥離	1 (5.6)	0	0	0
Grade 3	1 (5.6)	0	0	0
胃腸障害	1 (5.6)	3 (18.8)	0	3 (9.1)
Grade 1	0	3 (18.8)	0	3 (9.1)
Grade 2	1 (5.6)	0	0	0
腹部膨満	0	1 (6.3)	0	1 (3.0)
Grade 1	0	1 (6.3)	0	1 (3.0)
齲歯	0	1 (6.3)	0	1 (3.0)
Grade 1	0	1 (6.3)	0	1 (3.0)
腸炎	1 (5.6)	0	0	0
Grade 2	1 (5.6)	0	0	0
胃炎	1 (5.6)	0	0	0
Grade 2	1 (5.6)	0	0	0
胃腸粘膜障害	0	1 (6.3)	0	1 (3.0)
Grade 1	0	1 (6.3)	0	1 (3.0)

Note: Treatment-emergent adverse events in DB Period are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or no more than 30 days after the last dose of study drug in DB Period, whichever occurs firstly.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	Placebo + TCS (N=18) n (%)	Active UPA 15 mg QD + TCS (N=16) n (%)	Active UPA 30 mg QD + TCS (N=17) n (%)	Total (N=33) n (%)
一般・全身障害および投与部位の状態	0	1 (6.3)	2 (11.8)	3 (9.1)
Grade 1	0	1 (6.3)	2 (11.8)	3 (9.1)
胸痛	0	1 (6.3)	0	1 (3.0)
Grade 1	0	1 (6.3)	0	1 (3.0)
発熱	0	0	2 (11.8)	2 (6.1)
Grade 1	0	0	2 (11.8)	2 (6.1)
免疫系障害	1 (5.6)	0	0	0
Grade 1	1 (5.6)	0	0	0
季節性アレルギー	1 (5.6)	0	0	0
Grade 1	1 (5.6)	0	0	0
感染症および寄生虫症	7 (38.9)	9 (56.3)	6 (35.3)	15 (45.5)
Grade 1	2 (11.1)	2 (12.5)	3 (17.6)	5 (15.2)
Grade 2	5 (27.8)	7 (43.8)	3 (17.6)	10 (30.3)

Note: Treatment-emergent adverse events in DB Period are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or no more than 30 days after the last dose of study drug in DB Period, whichever occurs firstly.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	Placebo + TCS (N=18) n (%)	Active UPA 15 mg QD + TCS (N=16) n (%)	Active UPA 30 mg QD + TCS (N=17) n (%)	Total (N=33) n (%)
感染症および寄生虫症 (Cont.)				
蜂巣炎	1 (5.6)	0	0	0
Grade 2	1 (5.6)	0	0	0
心内膜炎	1 (5.6)	0	0	0
Grade 2	1 (5.6)	0	0	0
丹毒	2 (11.1)	0	0	0
Grade 2	2 (11.1)	0	0	0
毛包炎	0	1 (6.3)	1 (5.9)	2 (6.1)
Grade 1	0	1 (6.3)	1 (5.9)	2 (6.1)
麦粒腫	0	0	1 (5.9)	1 (3.0)
Grade 2	0	0	1 (5.9)	1 (3.0)
インフルエンザ	1 (5.6)	4 (25.0)	2 (11.8)	6 (18.2)
Grade 1	0	0	2 (11.8)	2 (6.1)
Grade 2	1 (5.6)	4 (25.0)	0	4 (12.1)
カポジ水痘様発疹	0	1 (6.3)	0	1 (3.0)
Grade 2	0	1 (6.3)	0	1 (3.0)

Note: Treatment-emergent adverse events in DB Period are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or no more than 30 days after the last dose of study drug in DB Period, whichever occurs firstly.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	Placebo + TCS (N=18) n (%)	Active UPA 15 mg QD + TCS (N=16) n (%)	Active UPA 30 mg QD + TCS (N=17) n (%)	Total (N=33) n (%)
感染症および寄生虫症 (Cont.)				
鼻ヘルペス	0	0	1 (5.9)	1 (3.0)
Grade 1	0	0	1 (5.9)	1 (3.0)
上咽頭炎	0	6 (37.5)	2 (11.8)	8 (24.2)
Grade 1	0	3 (18.8)	0	3 (9.1)
Grade 2	0	3 (18.8)	2 (11.8)	5 (15.2)
口腔ヘルペス	0	0	1 (5.9)	1 (3.0)
Grade 1	0	0	1 (5.9)	1 (3.0)
須毛瘡	1 (5.6)	0	0	0
Grade 1	1 (5.6)	0	0	0
癜風	1 (5.6)	0	0	0
Grade 1	1 (5.6)	0	0	0
上気道感染	2 (11.1)	0	0	0
Grade 1	1 (5.6)	0	0	0
Grade 2	1 (5.6)	0	0	0

Note: Treatment-emergent adverse events in DB Period are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or no more than 30 days after the last dose of study drug in DB Period, whichever occurs firstly.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	Placebo + TCS (N=18) n (%)	Active UPA 15 mg QD + TCS (N=16) n (%)	Active UPA 30 mg QD + TCS (N=17) n (%)	Total (N=33) n (%)
傷害、中毒および処置合併症	0	0	1 (5.9)	1 (3.0)
Grade 1	0	0	1 (5.9)	1 (3.0)
創傷	0	0	1 (5.9)	1 (3.0)
Grade 1	0	0	1 (5.9)	1 (3.0)
臨床検査	1 (5.6)	1 (6.3)	1 (5.9)	2 (6.1)
Grade 1	1 (5.6)	0	0	0
Grade 2	0	1 (6.3)	1 (5.9)	2 (6.1)
アラニンアミノトランスフェラーゼ増加	0	0	1 (5.9)	1 (3.0)
Grade 2	0	0	1 (5.9)	1 (3.0)
血中クレアチンホスホキナーゼ増加	1 (5.6)	0	0	0
Grade 1	1 (5.6)	0	0	0
血小板数減少	1 (5.6)	0	0	0
Grade 1	1 (5.6)	0	0	0

Note: Treatment-emergent adverse events in DB Period are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or no more than 30 days after the last dose of study drug in DB Period, whichever occurs firstly.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	Placebo + TCS (N=18) n (%)	Active UPA 15 mg QD + TCS (N=16) n (%)	Active UPA 30 mg QD + TCS (N=17) n (%)	Total (N=33) n (%)
臨床検査 (Cont.)				
血小板数増加	1 (5.6)	0	0	0
Grade 1	1 (5.6)	0	0	0
体重増加	0	1 (6.3)	0	1 (3.0)
Grade 2	0	1 (6.3)	0	1 (3.0)
神経系障害	1 (5.6)	0	1 (5.9)	1 (3.0)
Grade 1	1 (5.6)	0	1 (5.9)	1 (3.0)
脳梗塞	1 (5.6)	0	0	0
Grade 1	1 (5.6)	0	0	0
傾眠	0	0	1 (5.9)	1 (3.0)
Grade 1	0	0	1 (5.9)	1 (3.0)
呼吸器、胸郭および縦隔障害	0	2 (12.5)	1 (5.9)	3 (9.1)
Grade 1	0	0	1 (5.9)	1 (3.0)
Grade 2	0	2 (12.5)	0	2 (6.1)
喘息	0	1 (6.3)	0	1 (3.0)
Grade 2	0	1 (6.3)	0	1 (3.0)

Note: Treatment-emergent adverse events in DB Period are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or no more than 30 days after the last dose of study drug in DB Period, whichever occurs firstly.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	Placebo + TCS (N=18) n (%)	Active UPA 15 mg QD + TCS (N=16) n (%)	Active UPA 30 mg QD + TCS (N=17) n (%)	Total (N=33) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)				
咳嗽	0	1 (6.3)	0	1 (3.0)
Grade 2	0	1 (6.3)	0	1 (3.0)
鼻出血	0	0	1 (5.9)	1 (3.0)
Grade 1	0	0	1 (5.9)	1 (3.0)
皮膚および皮下組織障害	3 (16.7)	0	3 (17.6)	3 (9.1)
Grade 1	2 (11.1)	0	2 (11.8)	2 (6.1)
Grade 2	1 (5.6)	0	1 (5.9)	1 (3.0)
ざ瘡	2 (11.1)	0	3 (17.6)	3 (9.1)
Grade 1	1 (5.6)	0	2 (11.8)	2 (6.1)
Grade 2	1 (5.6)	0	1 (5.9)	1 (3.0)
脱毛症	1 (5.6)	0	0	0
Grade 1	1 (5.6)	0	0	0

Note: Treatment-emergent adverse events in DB Period are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or no more than 30 days after the last dose of study drug in DB Period, whichever occurs firstly.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

相互参照：M16-047 試験 W16 Japan data Table 14.3 1.12.1 J

表 2.7.4.7-132.　投与 52 週時データカットオフまでの全有害事象の集計表（ALL_UPA_M 集団，日本人集団）：M16-047 試験

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=24) n (%)	UPA 30 mg QD + TCS (N=26) n (%)	Total (N=50) n (%)
Any adverse event	21 (87.5)	22 (84.6)	43 (86.0)
血液およびリンパ系障害	2 (8.3)	1 (3.8)	3 (6.0)
貧血	1 (4.2)	0	1 (2.0)
リンパ節症	1 (4.2)	0	1 (2.0)
リンパ組織過形成	0	1 (3.8)	1 (2.0)
眼障害	3 (12.5)	1 (3.8)	4 (8.0)
アレルギー性結膜炎	1 (4.2)	0	1 (2.0)
角膜浮腫	1 (4.2)	0	1 (2.0)
ドライアイ	1 (4.2)	0	1 (2.0)
緑内障	1 (4.2)	0	1 (2.0)
視力低下	0	1 (3.8)	1 (2.0)
胃腸障害	6 (25.0)	3 (11.5)	9 (18.0)
腹部膨満	1 (4.2)	0	1 (2.0)
腹痛	1 (4.2)	0	1 (2.0)
上腹部痛	0	1 (3.8)	1 (2.0)
齲歯	3 (12.5)	1 (3.8)	4 (8.0)
胃炎	0	1 (3.8)	1 (2.0)

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

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=24) n (%)	UPA 30 mg QD + TCS (N=26) n (%)	Total (N=50) n (%)
胃腸障害 (Cont.)			
胃腸粘膜障害	1 (4.2)	0	1 (2.0)
悪心	1 (4.2)	0	1 (2.0)
歯周病	1 (4.2)	0	1 (2.0)
一般・全身障害および投与部位の状態	3 (12.5)	2 (7.7)	5 (10.0)
胸痛	1 (4.2)	0	1 (2.0)
末梢性浮腫	1 (4.2)	0	1 (2.0)
末梢腫脹	1 (4.2)	0	1 (2.0)
発熱	0	2 (7.7)	2 (4.0)
肝胆道系障害	1 (4.2)	0	1 (2.0)
脂肪肝	1 (4.2)	0	1 (2.0)
感染症および寄生虫症	19 (79.2)	20 (76.9)	39 (78.0)
気管支炎	0	1 (3.8)	1 (2.0)
蜂巣炎	1 (4.2)	1 (3.8)	2 (4.0)
丹毒	1 (4.2)	0	1 (2.0)
毛包炎	4 (16.7)	2 (7.7)	6 (12.0)
せつ	1 (4.2)	0	1 (2.0)
胃腸炎	1 (4.2)	1 (3.8)	2 (4.0)

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

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=24) n (%)	UPA 30 mg QD + TCS (N=26) n (%)	Total (N=50) n (%)
感染症および寄生虫症 (Cont.)			
単純ヘルペス	2 (8.3)	1 (3.8)	3 (6.0)
帯状疱疹	3 (12.5)	5 (19.2)	8 (16.0)
皮膚播種性帯状疱疹	1 (4.2)	0	1 (2.0)
麦粒腫	0	2 (7.7)	2 (4.0)
膿痂疹	2 (8.3)	0	2 (4.0)
感染性皮膚嚢腫	0	1 (3.8)	1 (2.0)
インフルエンザ	4 (16.7)	4 (15.4)	8 (16.0)
カポジ水痘様発疹	1 (4.2)	1 (3.8)	2 (4.0)
ウイルス性髄膜炎	1 (4.2)	0	1 (2.0)
鼻ヘルペス	0	1 (3.8)	1 (2.0)
上咽頭炎	13 (54.2)	7 (26.9)	20 (40.0)
口腔ヘルペス	0	1 (3.8)	1 (2.0)
外耳炎	0	1 (3.8)	1 (2.0)
爪囲炎	1 (4.2)	0	1 (2.0)
咽頭炎	0	1 (3.8)	1 (2.0)
膿疱	0	1 (3.8)	1 (2.0)
腎盂腎炎	1 (4.2)	0	1 (2.0)

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

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=24) n (%)	UPA 30 mg QD + TCS (N=26) n (%)	Total (N=50) n (%)
感染症および寄生虫症 (Cont.)			
足部白癬	1 (4.2)	3 (11.5)	4 (8.0)
癜風	0	1 (3.8)	1 (2.0)
扁桃炎	0	1 (3.8)	1 (2.0)
上気道感染	2 (8.3)	0	2 (4.0)
トリコモナス外陰腟炎	1 (4.2)	0	1 (2.0)
傷害、中毒および処置合併症	3 (12.5)	3 (11.5)	6 (12.0)
尾骨骨折	1 (4.2)	0	1 (2.0)
熱疲労	0	1 (3.8)	1 (2.0)
靭帯損傷	1 (4.2)	0	1 (2.0)
靭帯捻挫	1 (4.2)	0	1 (2.0)
肋骨骨折	0	1 (3.8)	1 (2.0)
創傷	0	1 (3.8)	1 (2.0)
臨床検査	2 (8.3)	4 (15.4)	6 (12.0)
アラニンアミノトランスフェラーゼ増加	1 (4.2)	1 (3.8)	2 (4.0)
アスパラギン酸アミノトランスフェラーゼ増加	1 (4.2)	0	1 (2.0)
血中クレアチンホスホキナーゼ増加	0	1 (3.8)	1 (2.0)
トランスアミナーゼ上昇	0	1 (3.8)	1 (2.0)

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

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=24) n (%)	UPA 30 mg QD + TCS (N=26) n (%)	Total (N=50) n (%)
臨床検査 (Cont.)			
体重増加	1 (4.2)	1 (3.8)	2 (4.0)
筋骨格系および結合組織障害	4 (16.7)	2 (7.7)	6 (12.0)
関節痛	1 (4.2)	0	1 (2.0)
関節炎	1 (4.2)	0	1 (2.0)
背部痛	2 (8.3)	1 (3.8)	3 (6.0)
椎間板突出	0	1 (3.8)	1 (2.0)
筋骨格痛	1 (4.2)	0	1 (2.0)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	4 (16.7)	0	4 (8.0)
結節性筋膜炎	1 (4.2)	0	1 (2.0)
皮膚乳頭腫	2 (8.3)	0	2 (4.0)
子宮平滑筋腫	1 (4.2)	0	1 (2.0)
神経系障害	3 (12.5)	2 (7.7)	5 (10.0)
浮動性めまい	1 (4.2)	0	1 (2.0)
頭痛	1 (4.2)	0	1 (2.0)
感覚鈍麻	1 (4.2)	0	1 (2.0)
末梢神経不全麻痺	1 (4.2)	0	1 (2.0)
ヘルペス後神経痛	1 (4.2)	1 (3.8)	2 (4.0)

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

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=24) n (%)	UPA 30 mg QD + TCS (N=26) n (%)	Total (N=50) n (%)
神経系障害 (Cont.)			
傾眠	0	1 (3.8)	1 (2.0)
足根管症候群	1 (4.2)	0	1 (2.0)
精神障害	0	2 (7.7)	2 (4.0)
不眠症	0	2 (7.7)	2 (4.0)
生殖系および乳房障害	0	1 (3.8)	1 (2.0)
不正子宮出血	0	1 (3.8)	1 (2.0)
呼吸器、胸郭および縦隔障害	3 (12.5)	2 (7.7)	5 (10.0)
喘息	1 (4.2)	0	1 (2.0)
咳嗽	2 (8.3)	0	2 (4.0)
鼻出血	0	2 (7.7)	2 (4.0)
皮膚および皮下組織障害	13 (54.2)	10 (38.5)	23 (46.0)
ざ瘡	8 (33.3)	8 (30.8)	16 (32.0)
水疱	0	1 (3.8)	1 (2.0)
皮膚嚢腫	0	1 (3.8)	1 (2.0)
アレルギー性皮膚炎	0	1 (3.8)	1 (2.0)
アトピー性皮膚炎	5 (20.8)	1 (3.8)	6 (12.0)
汗疹	2 (8.3)	0	2 (4.0)

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

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=24) n (%)	UPA 30 mg QD + TCS (N=26) n (%)	Total (N=50) n (%)
皮膚および皮下組織障害 (Cont.)			
口囲皮膚炎	1 (4.2)	0	1 (2.0)
皮膚腫瘤	1 (4.2)	0	1 (2.0)
皮膚潰瘍	1 (4.2)	0	1 (2.0)
蕁麻疹	2 (8.3)	1 (3.8)	3 (6.0)
血管障害	1 (4.2)	0	1 (2.0)
高血圧	1 (4.2)	0	1 (2.0)

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

相互参照：M16-047 試験 W52 Japan data Table 14.3 1.5.1.1 J

表 2.7.4.7-133.　投与 52 週時データカットオフまでの 100 人年あたりの全有害事象の集計表（ALL_UPA_M 集団，日本人集団）：M16-047 試験

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=24) (PYS=42.3) Events (E/100PY)	UPA 30 mg QD + TCS (N=26) (PYS=47.5) Events (E/100PY)	Total (N=50) (PYS=89.8) Events (E/100PY)
Any adverse event	124 (293.4)	76 (159.9)	200 (222.7)
血液およびリンパ系障害	3 (7.1)	1 (2.1)	4 (4.5)
貧血	2 (4.7)	0	2 (2.2)
リンパ節症	1 (2.4)	0	1 (1.1)
リンパ組織過形成	0	1 (2.1)	1 (1.1)
眼障害	4 (9.5)	1 (2.1)	5 (5.6)
アレルギー性結膜炎	1 (2.4)	0	1 (1.1)
角膜浮腫	1 (2.4)	0	1 (1.1)
ドライアイ	1 (2.4)	0	1 (1.1)
緑内障	1 (2.4)	0	1 (1.1)
視力低下	0	1 (2.1)	1 (1.1)
胃腸障害	8 (18.9)	3 (6.3)	11 (12.3)
腹部膨満	1 (2.4)	0	1 (1.1)
腹痛	1 (2.4)	0	1 (1.1)
上腹部痛	0	1 (2.1)	1 (1.1)
齲歯	3 (7.1)	1 (2.1)	4 (4.5)
胃炎	0	1 (2.1)	1 (1.1)

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.

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=24) (PYS=42.3) Events (E/100PY)	UPA 30 mg QD + TCS (N=26) (PYS=47.5) Events (E/100PY)	Total (N=50) (PYS=89.8) Events (E/100PY)
胃腸障害 (Cont.)			
胃腸粘膜障害	1 (2.4)	0	1 (1.1)
悪心	1 (2.4)	0	1 (1.1)
歯周病	1 (2.4)	0	1 (1.1)
一般・全身障害および投与部位の状態	3 (7.1)	2 (4.2)	5 (5.6)
胸痛	1 (2.4)	0	1 (1.1)
末梢性浮腫	1 (2.4)	0	1 (1.1)
末梢腫脹	1 (2.4)	0	1 (1.1)
発熱	0	2 (4.2)	2 (2.2)
肝胆道系障害	1 (2.4)	0	1 (1.1)
脂肪肝	1 (2.4)	0	1 (1.1)
感染症および寄生虫症	57 (134.9)	37 (77.8)	94 (104.7)
気管支炎	0	1 (2.1)	1 (1.1)
蜂巣炎	1 (2.4)	1 (2.1)	2 (2.2)
丹毒	1 (2.4)	0	1 (1.1)
毛包炎	4 (9.5)	2 (4.2)	6 (6.7)
せつ	1 (2.4)	0	1 (1.1)
胃腸炎	1 (2.4)	1 (2.1)	2 (2.2)

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.

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=24) (PYS=42.3) Events (E/100PY)	UPA 30 mg QD + TCS (N=26) (PYS=47.5) Events (E/100PY)	Total (N=50) (PYS=89.8) Events (E/100PY)
感染症および寄生虫症 (Cont.)			
単純ヘルペス	2 (4.7)	1 (2.1)	3 (3.3)
帯状疱疹	3 (7.1)	5 (10.5)	8 (8.9)
皮膚播種性帯状疱疹	1 (2.4)	0	1 (1.1)
麦粒腫	0	2 (4.2)	2 (2.2)
膿痂疹	2 (4.7)	0	2 (2.2)
感染性皮膚嚢腫	0	1 (2.1)	1 (1.1)
インフルエンザ	5 (11.8)	4 (8.4)	9 (10.0)
カポジ水痘様発疹	1 (2.4)	2 (4.2)	3 (3.3)
ウイルス性髄膜炎	1 (2.4)	0	1 (1.1)
鼻ヘルペス	0	1 (2.1)	1 (1.1)
上咽頭炎	27 (63.9)	7 (14.7)	34 (37.9)
口腔ヘルペス	0	1 (2.1)	1 (1.1)
外耳炎	0	1 (2.1)	1 (1.1)
爪囲炎	1 (2.4)	0	1 (1.1)
咽頭炎	0	1 (2.1)	1 (1.1)
膿疱	0	1 (2.1)	1 (1.1)
腎盂腎炎	1 (2.4)	0	1 (1.1)

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.

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=24) (PYS=42.3) Events (E/100PY)	UPA 30 mg QD + TCS (N=26) (PYS=47.5) Events (E/100PY)	Total (N=50) (PYS=89.8) Events (E/100PY)
感染症および寄生虫症 (Cont.)			
足部白癬	1 (2.4)	3 (6.3)	4 (4.5)
癜風	0	1 (2.1)	1 (1.1)
扁桃炎	0	1 (2.1)	1 (1.1)
上気道感染	3 (7.1)	0	3 (3.3)
トリコモナス外陰膣炎	1 (2.4)	0	1 (1.1)
傷害、中毒および処置合併症	4 (9.5)	3 (6.3)	7 (7.8)
尾骨骨折	1 (2.4)	0	1 (1.1)
熱疲労	0	1 (2.1)	1 (1.1)
靭帯損傷	2 (4.7)	0	2 (2.2)
靭帯捻挫	1 (2.4)	0	1 (1.1)
肋骨骨折	0	1 (2.1)	1 (1.1)
創傷	0	1 (2.1)	1 (1.1)
臨床検査	3 (7.1)	5 (10.5)	8 (8.9)
アラニンアミノトランスフェラーゼ増加	1 (2.4)	1 (2.1)	2 (2.2)
アスパラギン酸アミノトランスフェラーゼ増加	1 (2.4)	0	1 (1.1)
血中クレアチンホスホキナーゼ増加	0	1 (2.1)	1 (1.1)
トランスアミナーゼ上昇	0	2 (4.2)	2 (2.2)

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.

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=24) (PYS=42.3) Events (E/100PY)	UPA 30 mg QD + TCS (N=26) (PYS=47.5) Events (E/100PY)	Total (N=50) (PYS=89.8) Events (E/100PY)
臨床検査 (Cont.)			
体重増加	1 (2.4)	1 (2.1)	2 (2.2)
筋骨格系および結合組織障害	5 (11.8)	2 (4.2)	7 (7.8)
関節痛	1 (2.4)	0	1 (1.1)
関節炎	1 (2.4)	0	1 (1.1)
背部痛	2 (4.7)	1 (2.1)	3 (3.3)
椎間板突出	0	1 (2.1)	1 (1.1)
筋骨格痛	1 (2.4)	0	1 (1.1)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	4 (9.5)	0	4 (4.5)
結節性筋膜炎	1 (2.4)	0	1 (1.1)
皮膚乳頭腫	2 (4.7)	0	2 (2.2)
子宮平滑筋腫	1 (2.4)	0	1 (1.1)
神経系障害	7 (16.6)	2 (4.2)	9 (10.0)
浮動性めまい	1 (2.4)	0	1 (1.1)
頭痛	1 (2.4)	0	1 (1.1)
感覚鈍麻	1 (2.4)	0	1 (1.1)
末梢神経不全麻痺	2 (4.7)	0	2 (2.2)
ヘルペス後神経痛	1 (2.4)	1 (2.1)	2 (2.2)

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.

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=24) (PYS=42.3) Events (E/100PY)	UPA 30 mg QD + TCS (N=26) (PYS=47.5) Events (E/100PY)	Total (N=50) (PYS=89.8) Events (E/100PY)
神経系障害 (Cont.)			
傾眠	0	1 (2.1)	1 (1.1)
足根管症候群	1 (2.4)	0	1 (1.1)
精神障害	0	2 (4.2)	2 (2.2)
不眠症	0	2 (4.2)	2 (2.2)
生殖系および乳房障害	0	1 (2.1)	1 (1.1)
不正子宮出血	0	1 (2.1)	1 (1.1)
呼吸器、胸郭および縦隔障害	3 (7.1)	2 (4.2)	5 (5.6)
喘息	1 (2.4)	0	1 (1.1)
咳嗽	2 (4.7)	0	2 (2.2)
鼻出血	0	2 (4.2)	2 (2.2)
皮膚および皮下組織障害	21 (49.7)	15 (31.6)	36 (40.1)
ざ瘡	8 (18.9)	10 (21.0)	18 (20.0)
水疱	0	1 (2.1)	1 (1.1)
皮膚嚢腫	0	1 (2.1)	1 (1.1)
アレルギー性皮膚炎	0	1 (2.1)	1 (1.1)
アトピー性皮膚炎	5 (11.8)	1 (2.1)	6 (6.7)
汗疹	3 (7.1)	0	3 (3.3)

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.

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=24) (PYS=42.3) Events (E/100PY)	UPA 30 mg QD + TCS (N=26) (PYS=47.5) Events (E/100PY)	Total (N=50) (PYS=89.8) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)			
口囲皮膚炎	1 (2.4)	0	1 (1.1)
皮膚腫瘤	1 (2.4)	0	1 (1.1)
皮膚潰瘍	1 (2.4)	0	1 (1.1)
蕁麻疹	2 (4.7)	1 (2.1)	3 (3.3)
血管障害	1 (2.4)	0	1 (1.1)
高血圧	1 (2.4)	0	1 (1.1)

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.

相互参照：M16-047 試験 W52 Japan data Table 14.3__1.5.2.1_J

表 2.7.4.7-134. 投与 52 週時データカットオフまでの治験薬と関連ありの有害事象の基本語別の集計表（ALL_UPA_M 集団，日本人集団）：M16-047 試験

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=24) n (%)	UPA 30 mg QD + TCS (N=26) n (%)	Total (N=50) n (%)
Any adverse event	12 (50.0)	11 (42.3)	23 (46.0)
血液およびリンパ系障害	1 (4.2)	0	1 (2.0)
貧血	1 (4.2)	0	1 (2.0)
胃腸障害	1 (4.2)	0	1 (2.0)
腹部膨満	1 (4.2)	0	1 (2.0)
一般・全身障害および投与部位の状態	0	1 (3.8)	1 (2.0)
発熱	0	1 (3.8)	1 (2.0)
感染症および寄生虫症	6 (25.0)	6 (23.1)	12 (24.0)
せつ	1 (4.2)	0	1 (2.0)
帯状疱疹	2 (8.3)	2 (7.7)	4 (8.0)
皮膚播種性帯状疱疹	1 (4.2)	0	1 (2.0)
麦粒腫	0	1 (3.8)	1 (2.0)
インフルエンザ	1 (4.2)	1 (3.8)	2 (4.0)
カポジ水痘様発疹	1 (4.2)	1 (3.8)	2 (4.0)
上咽頭炎	3 (12.5)	0	3 (6.0)
膿疱	0	1 (3.8)	1 (2.0)
足部白癬	0	1 (3.8)	1 (2.0)

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

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=24) n (%)	UPA 30 mg QD + TCS (N=26) n (%)	Total (N=50) n (%)
臨床検査	0	2 (7.7)	2 (4.0)
アラニンアミノトランスフェラーゼ増加	0	1 (3.8)	1 (2.0)
体重増加	0	1 (3.8)	1 (2.0)
神経系障害	0	1 (3.8)	1 (2.0)
傾眠	0	1 (3.8)	1 (2.0)
呼吸器、胸郭および縦隔障害	1 (4.2)	0	1 (2.0)
咳嗽	1 (4.2)	0	1 (2.0)
皮膚および皮下組織障害	4 (16.7)	6 (23.1)	10 (20.0)
ざ瘡	4 (16.7)	5 (19.2)	9 (18.0)
水疱	0	1 (3.8)	1 (2.0)

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

相互参照：M16-047 試験 W52 Japan data Table 14.3 1.8.1 J

表 2.7.4.7-135. 投与 52 週時データカットオフまでの 100 人年あたりの治験薬と関連ありの有害事象の基本語別の集計表（ALL_UPA_M 集団，日本人集団）：M16-047 試験

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=24) (PYS=42.3) Events (E/100PY)	UPA 30 mg QD + TCS (N=26) (PYS=47.5) Events (E/100PY)	Total (N=50) (PYS=89.8) Events (E/100PY)
Any adverse event	18 (42.6)	18 (37.9)	36 (40.1)
血液およびリンパ系障害	2 (4.7)	0	2 (2.2)
貧血	2 (4.7)	0	2 (2.2)
胃腸障害	1 (2.4)	0	1 (1.1)
腹部膨満	1 (2.4)	0	1 (1.1)
一般・全身障害および投与部位の状態	0	1 (2.1)	1 (1.1)
発熱	0	1 (2.1)	1 (1.1)
感染症および寄生虫症	10 (23.7)	8 (16.8)	18 (20.0)
せつ	1 (2.4)	0	1 (1.1)
帯状疱疹	2 (4.7)	2 (4.2)	4 (4.5)
皮膚播種性帯状疱疹	1 (2.4)	0	1 (1.1)
麦粒腫	0	1 (2.1)	1 (1.1)
インフルエンザ	1 (2.4)	1 (2.1)	2 (2.2)
カポジ水痘様発疹	1 (2.4)	2 (4.2)	3 (3.3)
上咽頭炎	4 (9.5)	0	4 (4.5)
膿疱	0	1 (2.1)	1 (1.1)
足部白癬	0	1 (2.1)	1 (1.1)

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.

MedDRA 22.1 System Organ Class Preferred Term	UPA 15 mg QD + TCS (N=24) (PYS=42.3) Events (E/100PY)	UPA 30 mg QD + TCS (N=26) (PYS=47.5) Events (E/100PY)	Total (N=50) (PYS=89.8) Events (E/100PY)
臨床検査	0	2 (4.2)	2 (2.2)
アラニンアミノトランスフェラーゼ増加	0	1 (2.1)	1 (1.1)
体重増加	0	1 (2.1)	1 (1.1)
神経系障害	0	1 (2.1)	1 (1.1)
傾眠	0	1 (2.1)	1 (1.1)
呼吸器、胸郭および縦隔障害	1 (2.4)	0	1 (1.1)
咳嗽	1 (2.4)	0	1 (1.1)
皮膚および皮下組織障害	4 (9.5)	6 (12.6)	10 (11.1)
ざ瘡	4 (9.5)	5 (10.5)	9 (10.0)
水疱	0	1 (2.1)	1 (1.1)

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.

相互参照：M16-047 試験 W52 Japan data Table 14.3 1.8.2 J

表 2.7.4.7-136. 投与 52 週時データカットオフまでの重症度別の有害事象の基本語別の集計表（ALL_UPA_M 集団，日本人集団）：M16-047 試験

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD + TCS (N=24) n (%)	UPA 30 mg QD + TCS (N=26) n (%)	Total (N=50) n (%)
Any adverse event	21 (87.5)	22 (84.6)	43 (86.0)
Grade 1	5 (20.8)	6 (23.1)	11 (22.0)
Grade 2	14 (58.3)	15 (57.7)	29 (58.0)
Grade 3	2 (8.3)	1 (3.8)	3 (6.0)
血液およびリンパ系障害	2 (8.3)	1 (3.8)	3 (6.0)
Grade 1	1 (4.2)	1 (3.8)	2 (4.0)
Grade 2	1 (4.2)	0	1 (2.0)
貧血	1 (4.2)	0	1 (2.0)
Grade 1	1 (4.2)	0	1 (2.0)
リンパ節症	1 (4.2)	0	1 (2.0)
Grade 2	1 (4.2)	0	1 (2.0)
リンパ組織過形成	0	1 (3.8)	1 (2.0)
Grade 1	0	1 (3.8)	1 (2.0)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD + TCS (N=24) n (%)	UPA 30 mg QD + TCS (N=26) n (%)	Total (N=50) n (%)
眼障害	3 (12.5)	1 (3.8)	4 (8.0)
Grade 1	2 (8.3)	1 (3.8)	3 (6.0)
Grade 2	1 (4.2)	0	1 (2.0)
アレルギー性結膜炎	1 (4.2)	0	1 (2.0)
Grade 1	1 (4.2)	0	1 (2.0)
角膜浮腫	1 (4.2)	0	1 (2.0)
Grade 1	1 (4.2)	0	1 (2.0)
ドライアイ	1 (4.2)	0	1 (2.0)
Grade 2	1 (4.2)	0	1 (2.0)
緑内障	1 (4.2)	0	1 (2.0)
Grade 2	1 (4.2)	0	1 (2.0)
視力低下	0	1 (3.8)	1 (2.0)
Grade 1	0	1 (3.8)	1 (2.0)
胃腸障害	6 (25.0)	3 (11.5)	9 (18.0)
Grade 1	4 (16.7)	3 (11.5)	7 (14.0)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD + TCS (N=24) n (%)	UPA 30 mg QD + TCS (N=26) n (%)	Total (N=50) n (%)
胃腸障害 (Cont.)			
Grade 2	2 (8.3)	0	2 (4.0)
腹部膨満	1 (4.2)	0	1 (2.0)
Grade 1	1 (4.2)	0	1 (2.0)
腹痛	1 (4.2)	0	1 (2.0)
Grade 1	1 (4.2)	0	1 (2.0)
上腹部痛	0	1 (3.8)	1 (2.0)
Grade 1	0	1 (3.8)	1 (2.0)
齲歯	3 (12.5)	1 (3.8)	4 (8.0)
Grade 1	1 (4.2)	1 (3.8)	2 (4.0)
Grade 2	2 (8.3)	0	2 (4.0)
胃炎	0	1 (3.8)	1 (2.0)
Grade 1	0	1 (3.8)	1 (2.0)
胃腸粘膜障害	1 (4.2)	0	1 (2.0)
Grade 1	1 (4.2)	0	1 (2.0)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD + TCS (N=24) n (%)	UPA 30 mg QD + TCS (N=26) n (%)	Total (N=50) n (%)
胃腸障害 (Cont.)			
悪心	1 (4.2)	0	1 (2.0)
Grade 1	1 (4.2)	0	1 (2.0)
歯周病	1 (4.2)	0	1 (2.0)
Grade 1	1 (4.2)	0	1 (2.0)
一般・全身障害および投与部位の状態	3 (12.5)	2 (7.7)	5 (10.0)
Grade 1	3 (12.5)	2 (7.7)	5 (10.0)
胸痛	1 (4.2)	0	1 (2.0)
Grade 1	1 (4.2)	0	1 (2.0)
末梢性浮腫	1 (4.2)	0	1 (2.0)
Grade 1	1 (4.2)	0	1 (2.0)
末梢腫脹	1 (4.2)	0	1 (2.0)
Grade 1	1 (4.2)	0	1 (2.0)
発熱	0	2 (7.7)	2 (4.0)
Grade 1	0	2 (7.7)	2 (4.0)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD + TCS (N=24) n (%)	UPA 30 mg QD + TCS (N=26) n (%)	Total (N=50) n (%)
肝胆道系障害	1 (4.2)	0	1 (2.0)
Grade 1	1 (4.2)	0	1 (2.0)
脂肪肝	1 (4.2)	0	1 (2.0)
Grade 1	1 (4.2)	0	1 (2.0)
感染症および寄生虫症	19 (79.2)	20 (76.9)	39 (78.0)
Grade 1	6 (25.0)	6 (23.1)	12 (24.0)
Grade 2	12 (50.0)	13 (50.0)	25 (50.0)
Grade 3	1 (4.2)	1 (3.8)	2 (4.0)
気管支炎	0	1 (3.8)	1 (2.0)
Grade 2	0	1 (3.8)	1 (2.0)
蜂巣炎	1 (4.2)	1 (3.8)	2 (4.0)
Grade 1	0	1 (3.8)	1 (2.0)
Grade 2	1 (4.2)	0	1 (2.0)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD + TCS (N=24) n (%)	UPA 30 mg QD + TCS (N=26) n (%)	Total (N=50) n (%)
感染症および寄生虫症 (Cont.)			
丹毒	1 (4.2)	0	1 (2.0)
Grade 2	1 (4.2)	0	1 (2.0)
毛包炎	4 (16.7)	2 (7.7)	6 (12.0)
Grade 1	3 (12.5)	1 (3.8)	4 (8.0)
Grade 2	1 (4.2)	1 (3.8)	2 (4.0)
せつ	1 (4.2)	0	1 (2.0)
Grade 2	1 (4.2)	0	1 (2.0)
胃腸炎	1 (4.2)	1 (3.8)	2 (4.0)
Grade 2	1 (4.2)	1 (3.8)	2 (4.0)
単純ヘルペス	2 (8.3)	1 (3.8)	3 (6.0)
Grade 1	1 (4.2)	0	1 (2.0)
Grade 2	1 (4.2)	1 (3.8)	2 (4.0)
帯状疱疹	3 (12.5)	5 (19.2)	8 (16.0)
Grade 1	0	2 (7.7)	2 (4.0)
Grade 2	3 (12.5)	2 (7.7)	5 (10.0)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD + TCS (N=24) n (%)	UPA 30 mg QD + TCS (N=26) n (%)	Total (N=50) n (%)
感染症および寄生虫症 (Cont.)			
帯状疱疹 (Cont.)			
Grade 3	0	1 (3.8)	1 (2.0)
皮膚播種性帯状疱疹	1 (4.2)	0	1 (2.0)
Grade 3	1 (4.2)	0	1 (2.0)
麦粒腫	0	2 (7.7)	2 (4.0)
Grade 1	0	1 (3.8)	1 (2.0)
Grade 2	0	1 (3.8)	1 (2.0)
膿痂疹	2 (8.3)	0	2 (4.0)
Grade 1	1 (4.2)	0	1 (2.0)
Grade 2	1 (4.2)	0	1 (2.0)
感染性皮膚嚢腫	0	1 (3.8)	1 (2.0)
Grade 2	0	1 (3.8)	1 (2.0)
インフルエンザ	4 (16.7)	4 (15.4)	8 (16.0)
Grade 1	0	3 (11.5)	3 (6.0)
Grade 2	4 (16.7)	1 (3.8)	5 (10.0)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD + TCS (N=24) n (%)	UPA 30 mg QD + TCS (N=26) n (%)	Total (N=50) n (%)
感染症および寄生虫症 (Cont.)			
カポジ水痘様発疹	1 (4.2)	1 (3.8)	2 (4.0)
Grade 2	1 (4.2)	1 (3.8)	2 (4.0)
ウイルス性髄膜炎	1 (4.2)	0	1 (2.0)
Grade 2	1 (4.2)	0	1 (2.0)
鼻ヘルペス	0	1 (3.8)	1 (2.0)
Grade 1	0	1 (3.8)	1 (2.0)
上咽頭炎	13 (54.2)	7 (26.9)	20 (40.0)
Grade 1	4 (16.7)	3 (11.5)	7 (14.0)
Grade 2	9 (37.5)	4 (15.4)	13 (26.0)
口腔ヘルペス	0	1 (3.8)	1 (2.0)
Grade 1	0	1 (3.8)	1 (2.0)
外耳炎	0	1 (3.8)	1 (2.0)
Grade 2	0	1 (3.8)	1 (2.0)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD + TCS (N=24) n (%)	UPA 30 mg QD + TCS (N=26) n (%)	Total (N=50) n (%)
感染症および寄生虫症 (Cont.)			
爪囲炎	1 (4.2)	0	1 (2.0)
Grade 2	1 (4.2)	0	1 (2.0)
咽頭炎	0	1 (3.8)	1 (2.0)
Grade 2	0	1 (3.8)	1 (2.0)
膿疱	0	1 (3.8)	1 (2.0)
Grade 2	0	1 (3.8)	1 (2.0)
腎盂腎炎	1 (4.2)	0	1 (2.0)
Grade 2	1 (4.2)	0	1 (2.0)
足部白癬	1 (4.2)	3 (11.5)	4 (8.0)
Grade 1	1 (4.2)	2 (7.7)	3 (6.0)
Grade 2	0	1 (3.8)	1 (2.0)
癜風	0	1 (3.8)	1 (2.0)
Grade 1	0	1 (3.8)	1 (2.0)
扁桃炎	0	1 (3.8)	1 (2.0)
Grade 2	0	1 (3.8)	1 (2.0)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD + TCS (N=24) n (%)	UPA 30 mg QD + TCS (N=26) n (%)	Total (N=50) n (%)
感染症および寄生虫症 (Cont.)			
上気道感染	2 (8.3)	0	2 (4.0)
Grade 1	2 (8.3)	0	2 (4.0)
トリコモナス外陰腟炎	1 (4.2)	0	1 (2.0)
Grade 2	1 (4.2)	0	1 (2.0)
傷害、中毒および処置合併症	3 (12.5)	3 (11.5)	6 (12.0)
Grade 1	0	3 (11.5)	3 (6.0)
Grade 2	2 (8.3)	0	2 (4.0)
Grade 3	1 (4.2)	0	1 (2.0)
尾骨骨折	1 (4.2)	0	1 (2.0)
Grade 2	1 (4.2)	0	1 (2.0)
熱疲労	0	1 (3.8)	1 (2.0)
Grade 1	0	1 (3.8)	1 (2.0)
靭帯損傷	1 (4.2)	0	1 (2.0)
Grade 3	1 (4.2)	0	1 (2.0)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD + TCS (N=24) n (%)	UPA 30 mg QD + TCS (N=26) n (%)	Total (N=50) n (%)
傷害、中毒および処置合併症 (Cont.)			
靭帯捻挫	1 (4.2)	0	1 (2.0)
Grade 2	1 (4.2)	0	1 (2.0)
肋骨骨折	0	1 (3.8)	1 (2.0)
Grade 1	0	1 (3.8)	1 (2.0)
創傷	0	1 (3.8)	1 (2.0)
Grade 1	0	1 (3.8)	1 (2.0)
臨床検査	2 (8.3)	4 (15.4)	6 (12.0)
Grade 2	2 (8.3)	4 (15.4)	6 (12.0)
アラニンアミノトランスフェラーゼ増加	1 (4.2)	1 (3.8)	2 (4.0)
Grade 2	1 (4.2)	1 (3.8)	2 (4.0)
アスパラギン酸アミノトランスフェラーゼ増加	1 (4.2)	0	1 (2.0)
Grade 2	1 (4.2)	0	1 (2.0)
血中クレアチンホスホキナーゼ増加	0	1 (3.8)	1 (2.0)
Grade 2	0	1 (3.8)	1 (2.0)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD + TCS (N=24) n (%)	UPA 30 mg QD + TCS (N=26) n (%)	Total (N=50) n (%)
臨床検査 (Cont.)			
トランスアミナーゼ上昇	0	1 (3.8)	1 (2.0)
Grade 2	0	1 (3.8)	1 (2.0)
体重増加	1 (4.2)	1 (3.8)	2 (4.0)
Grade 2	1 (4.2)	1 (3.8)	2 (4.0)
筋骨格系および結合組織障害	4 (16.7)	2 (7.7)	6 (12.0)
Grade 1	1 (4.2)	0	1 (2.0)
Grade 2	3 (12.5)	2 (7.7)	5 (10.0)
関節痛	1 (4.2)	0	1 (2.0)
Grade 2	1 (4.2)	0	1 (2.0)
関節炎	1 (4.2)	0	1 (2.0)
Grade 2	1 (4.2)	0	1 (2.0)
背部痛	2 (8.3)	1 (3.8)	3 (6.0)
Grade 1	1 (4.2)	0	1 (2.0)
Grade 2	1 (4.2)	1 (3.8)	2 (4.0)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD + TCS (N=24) n (%)	UPA 30 mg QD + TCS (N=26) n (%)	Total (N=50) n (%)
筋骨格系および結合組織障害 (Cont.)			
椎間板突出	0	1 (3.8)	1 (2.0)
Grade 2	0	1 (3.8)	1 (2.0)
筋骨格痛	1 (4.2)	0	1 (2.0)
Grade 2	1 (4.2)	0	1 (2.0)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	4 (16.7)	0	4 (8.0)
Grade 1	2 (8.3)	0	2 (4.0)
Grade 2	2 (8.3)	0	2 (4.0)
結節性筋膜炎	1 (4.2)	0	1 (2.0)
Grade 1	1 (4.2)	0	1 (2.0)
皮膚乳頭腫	2 (8.3)	0	2 (4.0)
Grade 1	1 (4.2)	0	1 (2.0)
Grade 2	1 (4.2)	0	1 (2.0)
子宮平滑筋腫	1 (4.2)	0	1 (2.0)
Grade 2	1 (4.2)	0	1 (2.0)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD + TCS (N=24) n (%)	UPA 30 mg QD + TCS (N=26) n (%)	Total (N=50) n (%)
神経系障害	3 (12.5)	2 (7.7)	5 (10.0)
Grade 1	1 (4.2)	1 (3.8)	2 (4.0)
Grade 2	1 (4.2)	1 (3.8)	2 (4.0)
Grade 3	1 (4.2)	0	1 (2.0)
浮動性めまい	1 (4.2)	0	1 (2.0)
Grade 1	1 (4.2)	0	1 (2.0)
頭痛	1 (4.2)	0	1 (2.0)
Grade 1	1 (4.2)	0	1 (2.0)
感覚鈍麻	1 (4.2)	0	1 (2.0)
Grade 1	1 (4.2)	0	1 (2.0)
末梢神経不全麻痺	1 (4.2)	0	1 (2.0)
Grade 3	1 (4.2)	0	1 (2.0)
ヘルペス後神経痛	1 (4.2)	1 (3.8)	2 (4.0)
Grade 2	1 (4.2)	1 (3.8)	2 (4.0)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD + TCS (N=24) n (%)	UPA 30 mg QD + TCS (N=26) n (%)	Total (N=50) n (%)
神経系障害 (Cont.)			
傾眠	0	1 (3.8)	1 (2.0)
Grade 1	0	1 (3.8)	1 (2.0)
足根管症候群	1 (4.2)	0	1 (2.0)
Grade 3	1 (4.2)	0	1 (2.0)
精神障害	0	2 (7.7)	2 (4.0)
Grade 1	0	2 (7.7)	2 (4.0)
不眠症	0	2 (7.7)	2 (4.0)
Grade 1	0	2 (7.7)	2 (4.0)
生殖系および乳房障害	0	1 (3.8)	1 (2.0)
Grade 1	0	1 (3.8)	1 (2.0)
不正子宮出血	0	1 (3.8)	1 (2.0)
Grade 1	0	1 (3.8)	1 (2.0)
呼吸器、胸郭および縦隔障害	3 (12.5)	2 (7.7)	5 (10.0)
Grade 1	1 (4.2)	1 (3.8)	2 (4.0)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD + TCS (N=24) n (%)	UPA 30 mg QD + TCS (N=26) n (%)	Total (N=50) n (%)
呼吸器、胸郭および縦隔障害 (Cont.)			
Grade 2	2 (8.3)	1 (3.8)	3 (6.0)
喘息	1 (4.2)	0	1 (2.0)
Grade 2	1 (4.2)	0	1 (2.0)
咳嗽	2 (8.3)	0	2 (4.0)
Grade 1	1 (4.2)	0	1 (2.0)
Grade 2	1 (4.2)	0	1 (2.0)
鼻出血	0	2 (7.7)	2 (4.0)
Grade 1	0	1 (3.8)	1 (2.0)
Grade 2	0	1 (3.8)	1 (2.0)
皮膚および皮下組織障害	13 (54.2)	10 (38.5)	23 (46.0)
Grade 1	6 (25.0)	5 (19.2)	11 (22.0)
Grade 2	7 (29.2)	5 (19.2)	12 (24.0)
ざ瘡	8 (33.3)	8 (30.8)	16 (32.0)
Grade 1	6 (25.0)	5 (19.2)	11 (22.0)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD + TCS (N=24) n (%)	UPA 30 mg QD + TCS (N=26) n (%)	Total (N=50) n (%)
皮膚および皮下組織障害 (Cont.)			
ざ瘡 (Cont.)			
Grade 2	2 (8.3)	3 (11.5)	5 (10.0)
水疱	0	1 (3.8)	1 (2.0)
Grade 2	0	1 (3.8)	1 (2.0)
皮膚嚢腫	0	1 (3.8)	1 (2.0)
Grade 2	0	1 (3.8)	1 (2.0)
アレルギー性皮膚炎	0	1 (3.8)	1 (2.0)
Grade 2	0	1 (3.8)	1 (2.0)
アトピー性皮膚炎	5 (20.8)	1 (3.8)	6 (12.0)
Grade 1	3 (12.5)	1 (3.8)	4 (8.0)
Grade 2	2 (8.3)	0	2 (4.0)
汗疹	2 (8.3)	0	2 (4.0)
Grade 1	2 (8.3)	0	2 (4.0)
口囲皮膚炎	1 (4.2)	0	1 (2.0)
Grade 2	1 (4.2)	0	1 (2.0)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD + TCS (N=24) n (%)	UPA 30 mg QD + TCS (N=26) n (%)	Total (N=50) n (%)
皮膚および皮下組織障害 (Cont.)			
皮膚腫瘤	1 (4.2)	0	1 (2.0)
Grade 2	1 (4.2)	0	1 (2.0)
皮膚潰瘍	1 (4.2)	0	1 (2.0)
Grade 2	1 (4.2)	0	1 (2.0)
蕁麻疹	2 (8.3)	1 (3.8)	3 (6.0)
Grade 1	1 (4.2)	1 (3.8)	2 (4.0)
Grade 2	1 (4.2)	0	1 (2.0)
血管障害	1 (4.2)	0	1 (2.0)
Grade 1	1 (4.2)	0	1 (2.0)
高血圧	1 (4.2)	0	1 (2.0)
Grade 1	1 (4.2)	0	1 (2.0)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject. Subjects are counted once in each row, regardless of the number of events they may have had.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

相互参照：M16-047 試験 W52 Japan data Table 14.3 1.10.1 J

表 2.7.4.7-137. 投与 52 週時データカットオフまでの 100 人年あたりの重症度別の有害事象の基本語別の集計表（ALL_UPA_M 集団，日本人集団）：M16-047 試験

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD + TCS (N=24) (PYS=42.3) Events (E/100PY)	UPA 30 mg QD + TCS (N=26) (PYS=47.5) Events (E/100PY)	Total (N=50) (PYS=89.8) Events (E/100PY)
Any adverse event	124 (293.4)	76 (159.9)	200 (222.7)
Grade 1	56 (132.5)	41 (86.3)	97 (108.0)
Grade 2	64 (151.5)	34 (71.5)	98 (109.1)
Grade 3	4 (9.5)	1 (2.1)	5 (5.6)
血液およびリンパ系障害	3 (7.1)	1 (2.1)	4 (4.5)
Grade 1	2 (4.7)	1 (2.1)	3 (3.3)
Grade 2	1 (2.4)	0	1 (1.1)
貧血	2 (4.7)	0	2 (2.2)
Grade 1	2 (4.7)	0	2 (2.2)
リンパ節症	1 (2.4)	0	1 (1.1)
Grade 2	1 (2.4)	0	1 (1.1)
リンパ組織過形成	0	1 (2.1)	1 (1.1)
Grade 1	0	1 (2.1)	1 (1.1)
眼障害	4 (9.5)	1 (2.1)	5 (5.6)
Grade 1	2 (4.7)	1 (2.1)	3 (3.3)
Grade 2	2 (4.7)	0	2 (2.2)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject.
E/100PY = Events per 100 patient-years.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD + TCS (N=24) (PYS=42.3) Events (E/100PY)	UPA 30 mg QD + TCS (N=26) (PYS=47.5) Events (E/100PY)	Total (N=50) (PYS=89.8) Events (E/100PY)
眼障害 (Cont.)			
アレルギー性結膜炎	1 (2.4)	0	1 (1.1)
Grade 1	1 (2.4)	0	1 (1.1)
角膜浮腫	1 (2.4)	0	1 (1.1)
Grade 1	1 (2.4)	0	1 (1.1)
ドライアイ	1 (2.4)	0	1 (1.1)
Grade 2	1 (2.4)	0	1 (1.1)
緑内障	1 (2.4)	0	1 (1.1)
Grade 2	1 (2.4)	0	1 (1.1)
視力低下	0	1 (2.1)	1 (1.1)
Grade 1	0	1 (2.1)	1 (1.1)
胃腸障害	8 (18.9)	3 (6.3)	11 (12.3)
Grade 1	6 (14.2)	3 (6.3)	9 (10.0)
Grade 2	2 (4.7)	0	2 (2.2)
腹部膨満	1 (2.4)	0	1 (1.1)
Grade 1	1 (2.4)	0	1 (1.1)
腹痛	1 (2.4)	0	1 (1.1)
Grade 1	1 (2.4)	0	1 (1.1)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject.
E/100PY = Events per 100 patient-years.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD + TCS (N=24) (PYS=42.3) Events (E/100PY)	UPA 30 mg QD + TCS (N=26) (PYS=47.5) Events (E/100PY)	Total (N=50) (PYS=89.8) Events (E/100PY)
胃腸障害 (Cont.)			
上腹部痛	0	1 (2.1)	1 (1.1)
Grade 1	0	1 (2.1)	1 (1.1)
齲歯	3 (7.1)	1 (2.1)	4 (4.5)
Grade 1	1 (2.4)	1 (2.1)	2 (2.2)
Grade 2	2 (4.7)	0	2 (2.2)
胃炎	0	1 (2.1)	1 (1.1)
Grade 1	0	1 (2.1)	1 (1.1)
胃腸粘膜障害	1 (2.4)	0	1 (1.1)
Grade 1	1 (2.4)	0	1 (1.1)
悪心	1 (2.4)	0	1 (1.1)
Grade 1	1 (2.4)	0	1 (1.1)
歯周病	1 (2.4)	0	1 (1.1)
Grade 1	1 (2.4)	0	1 (1.1)
一般・全身障害および投与部位の状態	3 (7.1)	2 (4.2)	5 (5.6)
Grade 1	3 (7.1)	2 (4.2)	5 (5.6)
胸痛	1 (2.4)	0	1 (1.1)
Grade 1	1 (2.4)	0	1 (1.1)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject.
E/100PY = Events per 100 patient-years.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD + TCS (N=24) (PYS=42.3) Events (E/100PY)	UPA 30 mg QD + TCS (N=26) (PYS=47.5) Events (E/100PY)	Total (N=50) (PYS=89.8) Events (E/100PY)
一般・全身障害および投与部位の状態 (Cont.)			
末梢性浮腫	1 (2.4)	0	1 (1.1)
Grade 1	1 (2.4)	0	1 (1.1)
末梢腫脹	1 (2.4)	0	1 (1.1)
Grade 1	1 (2.4)	0	1 (1.1)
発熱	0	2 (4.2)	2 (2.2)
Grade 1	0	2 (4.2)	2 (2.2)
肝胆道系障害	1 (2.4)	0	1 (1.1)
Grade 1	1 (2.4)	0	1 (1.1)
脂肪肝	1 (2.4)	0	1 (1.1)
Grade 1	1 (2.4)	0	1 (1.1)
感染症および寄生虫症	57 (134.9)	37 (77.8)	94 (104.7)
Grade 1	19 (45.0)	16 (33.7)	35 (39.0)
Grade 2	37 (87.6)	20 (42.1)	57 (63.5)
Grade 3	1 (2.4)	1 (2.1)	2 (2.2)
気管支炎	0	1 (2.1)	1 (1.1)
Grade 2	0	1 (2.1)	1 (1.1)
蜂巣炎	1 (2.4)	1 (2.1)	2 (2.2)
Grade 1	0	1 (2.1)	1 (1.1)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject.
E/100PY = Events per 100 patient-years.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD + TCS (N=24) (PYS=42.3) Events (E/100PY)	UPA 30 mg QD + TCS (N=26) (PYS=47.5) Events (E/100PY)	Total (N=50) (PYS=89.8) Events (E/100PY)
感染症および寄生虫症 (Cont.)			
蜂巣炎 (Cont.)			
Grade 2	1 (2.4)	0	1 (1.1)
丹毒	1 (2.4)	0	1 (1.1)
Grade 2	1 (2.4)	0	1 (1.1)
毛包炎	4 (9.5)	2 (4.2)	6 (6.7)
Grade 1	3 (7.1)	1 (2.1)	4 (4.5)
Grade 2	1 (2.4)	1 (2.1)	2 (2.2)
せつ	1 (2.4)	0	1 (1.1)
Grade 2	1 (2.4)	0	1 (1.1)
胃腸炎	1 (2.4)	1 (2.1)	2 (2.2)
Grade 2	1 (2.4)	1 (2.1)	2 (2.2)
単純ヘルペス	2 (4.7)	1 (2.1)	3 (3.3)
Grade 1	1 (2.4)	0	1 (1.1)
Grade 2	1 (2.4)	1 (2.1)	2 (2.2)
帯状疱疹	3 (7.1)	5 (10.5)	8 (8.9)
Grade 1	0	2 (4.2)	2 (2.2)
Grade 2	3 (7.1)	2 (4.2)	5 (5.6)
Grade 3	0	1 (2.1)	1 (1.1)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject.
E/100PY = Events per 100 patient-years.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD + TCS (N=24) (PYS=42.3) Events (E/100PY)	UPA 30 mg QD + TCS (N=26) (PYS=47.5) Events (E/100PY)	Total (N=50) (PYS=89.8) Events (E/100PY)
感染症および寄生虫症 (Cont.)			
皮膚播種性帯状疱疹	1 (2.4)	0	1 (1.1)
Grade 3	1 (2.4)	0	1 (1.1)
麦粒腫	0	2 (4.2)	2 (2.2)
Grade 1	0	1 (2.1)	1 (1.1)
Grade 2	0	1 (2.1)	1 (1.1)
膿痂疹	2 (4.7)	0	2 (2.2)
Grade 1	1 (2.4)	0	1 (1.1)
Grade 2	1 (2.4)	0	1 (1.1)
感染性皮膚嚢腫	0	1 (2.1)	1 (1.1)
Grade 2	0	1 (2.1)	1 (1.1)
インフルエンザ	5 (11.8)	4 (8.4)	9 (10.0)
Grade 1	0	3 (6.3)	3 (3.3)
Grade 2	5 (11.8)	1 (2.1)	6 (6.7)
カポジ水痘様発疹	1 (2.4)	2 (4.2)	3 (3.3)
Grade 2	1 (2.4)	2 (4.2)	3 (3.3)
ウイルス性髄膜炎	1 (2.4)	0	1 (1.1)
Grade 2	1 (2.4)	0	1 (1.1)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject.
E/100PY = Events per 100 patient-years.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD + TCS (N=24) (PYS=42.3) Events (E/100PY)	UPA 30 mg QD + TCS (N=26) (PYS=47.5) Events (E/100PY)	Total (N=50) (PYS=89.8) Events (E/100PY)
感染症および寄生虫症 (Cont.)			
鼻ヘルペス	0	1 (2.1)	1 (1.1)
Grade 1	0	1 (2.1)	1 (1.1)
上咽頭炎	27 (63.9)	7 (14.7)	34 (37.9)
Grade 1	10 (23.7)	3 (6.3)	13 (14.5)
Grade 2	17 (40.2)	4 (8.4)	21 (23.4)
口腔ヘルペス	0	1 (2.1)	1 (1.1)
Grade 1	0	1 (2.1)	1 (1.1)
外耳炎	0	1 (2.1)	1 (1.1)
Grade 2	0	1 (2.1)	1 (1.1)
爪囲炎	1 (2.4)	0	1 (1.1)
Grade 2	1 (2.4)	0	1 (1.1)
咽頭炎	0	1 (2.1)	1 (1.1)
Grade 2	0	1 (2.1)	1 (1.1)
膿疱	0	1 (2.1)	1 (1.1)
Grade 2	0	1 (2.1)	1 (1.1)
腎盂腎炎	1 (2.4)	0	1 (1.1)
Grade 2	1 (2.4)	0	1 (1.1)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject.
E/100PY = Events per 100 patient-years.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD + TCS (N=24) (PYS=42.3) Events (E/100PY)	UPA 30 mg QD + TCS (N=26) (PYS=47.5) Events (E/100PY)	Total (N=50) (PYS=89.8) Events (E/100PY)
感染症および寄生虫症 (Cont.)			
足部白癬	1 (2.4)	3 (6.3)	4 (4.5)
Grade 1	1 (2.4)	2 (4.2)	3 (3.3)
Grade 2	0	1 (2.1)	1 (1.1)
癜風	0	1 (2.1)	1 (1.1)
Grade 1	0	1 (2.1)	1 (1.1)
扁桃炎	0	1 (2.1)	1 (1.1)
Grade 2	0	1 (2.1)	1 (1.1)
上気道感染	3 (7.1)	0	3 (3.3)
Grade 1	3 (7.1)	0	3 (3.3)
トリコモナス外陰腟炎	1 (2.4)	0	1 (1.1)
Grade 2	1 (2.4)	0	1 (1.1)
傷害、中毒および処置合併症	4 (9.5)	3 (6.3)	7 (7.8)
Grade 1	1 (2.4)	3 (6.3)	4 (4.5)
Grade 2	2 (4.7)	0	2 (2.2)
Grade 3	1 (2.4)	0	1 (1.1)
尾骨骨折	1 (2.4)	0	1 (1.1)
Grade 2	1 (2.4)	0	1 (1.1)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject.
E/100PY = Events per 100 patient-years.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD + TCS (N=24) (PYS=42.3) Events (E/100PY)	UPA 30 mg QD + TCS (N=26) (PYS=47.5) Events (E/100PY)	Total (N=50) (PYS=89.8) Events (E/100PY)
傷害、中毒および処置合併症 (Cont.)			
熱疲労	0	1 (2.1)	1 (1.1)
Grade 1	0	1 (2.1)	1 (1.1)
靭帯損傷	2 (4.7)	0	2 (2.2)
Grade 1	1 (2.4)	0	1 (1.1)
Grade 3	1 (2.4)	0	1 (1.1)
靭帯捻挫	1 (2.4)	0	1 (1.1)
Grade 2	1 (2.4)	0	1 (1.1)
肋骨骨折	0	1 (2.1)	1 (1.1)
Grade 1	0	1 (2.1)	1 (1.1)
創傷	0	1 (2.1)	1 (1.1)
Grade 1	0	1 (2.1)	1 (1.1)
臨床検査	3 (7.1)	5 (10.5)	8 (8.9)
Grade 1	0	1 (2.1)	1 (1.1)
Grade 2	3 (7.1)	4 (8.4)	7 (7.8)
アラニンアミノトランスフェラーゼ増加	1 (2.4)	1 (2.1)	2 (2.2)
Grade 2	1 (2.4)	1 (2.1)	2 (2.2)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject.
E/100PY = Events per 100 patient-years.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD + TCS (N=24) (PYS=42.3) Events (E/100PY)	UPA 30 mg QD + TCS (N=26) (PYS=47.5) Events (E/100PY)	Total (N=50) (PYS=89.8) Events (E/100PY)
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	1 (2.4)	0	1 (1.1)
Grade 2	1 (2.4)	0	1 (1.1)
血中クレアチンホスホキナーゼ増加	0	1 (2.1)	1 (1.1)
Grade 2	0	1 (2.1)	1 (1.1)
トランスアミナーゼ上昇	0	2 (4.2)	2 (2.2)
Grade 1	0	1 (2.1)	1 (1.1)
Grade 2	0	1 (2.1)	1 (1.1)
体重増加	1 (2.4)	1 (2.1)	2 (2.2)
Grade 2	1 (2.4)	1 (2.1)	2 (2.2)
筋骨格系および結合組織障害	5 (11.8)	2 (4.2)	7 (7.8)
Grade 1	1 (2.4)	0	1 (1.1)
Grade 2	4 (9.5)	2 (4.2)	6 (6.7)
関節痛	1 (2.4)	0	1 (1.1)
Grade 2	1 (2.4)	0	1 (1.1)
関節炎	1 (2.4)	0	1 (1.1)
Grade 2	1 (2.4)	0	1 (1.1)
背部痛	2 (4.7)	1 (2.1)	3 (3.3)
Grade 1	1 (2.4)	0	1 (1.1)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject.
E/100PY = Events per 100 patient-years.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD + TCS (N=24) (PYS=42.3) Events (E/100PY)	UPA 30 mg QD + TCS (N=26) (PYS=47.5) Events (E/100PY)	Total (N=50) (PYS=89.8) Events (E/100PY)
筋骨格系および結合組織障害 (Cont.)			
背部痛 (Cont.)			
Grade 2	1 (2.4)	1 (2.1)	2 (2.2)
椎間板突出	0	1 (2.1)	1 (1.1)
Grade 2	0	1 (2.1)	1 (1.1)
筋骨格痛	1 (2.4)	0	1 (1.1)
Grade 2	1 (2.4)	0	1 (1.1)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	4 (9.5)	0	4 (4.5)
Grade 1	2 (4.7)	0	2 (2.2)
Grade 2	2 (4.7)	0	2 (2.2)
結節性筋膜炎	1 (2.4)	0	1 (1.1)
Grade 1	1 (2.4)	0	1 (1.1)
皮膚乳頭腫	2 (4.7)	0	2 (2.2)
Grade 1	1 (2.4)	0	1 (1.1)
Grade 2	1 (2.4)	0	1 (1.1)
子宮平滑筋腫	1 (2.4)	0	1 (1.1)
Grade 2	1 (2.4)	0	1 (1.1)
神経系障害	7 (16.6)	2 (4.2)	9 (10.0)
Grade 1	4 (9.5)	1 (2.1)	5 (5.6)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject.
E/100PY = Events per 100 patient-years.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD + TCS (N=24) (PYS=42.3) Events (E/100PY)	UPA 30 mg QD + TCS (N=26) (PYS=47.5) Events (E/100PY)	Total (N=50) (PYS=89.8) Events (E/100PY)
神経系障害 (Cont.)			
Grade 2	1 (2.4)	1 (2.1)	2 (2.2)
Grade 3	2 (4.7)	0	2 (2.2)
浮動性めまい	1 (2.4)	0	1 (1.1)
Grade 1	1 (2.4)	0	1 (1.1)
頭痛	1 (2.4)	0	1 (1.1)
Grade 1	1 (2.4)	0	1 (1.1)
感覚鈍麻	1 (2.4)	0	1 (1.1)
Grade 1	1 (2.4)	0	1 (1.1)
末梢神経不全麻痺	2 (4.7)	0	2 (2.2)
Grade 1	1 (2.4)	0	1 (1.1)
Grade 3	1 (2.4)	0	1 (1.1)
ヘルペス後神経痛	1 (2.4)	1 (2.1)	2 (2.2)
Grade 2	1 (2.4)	1 (2.1)	2 (2.2)
傾眠	0	1 (2.1)	1 (1.1)
Grade 1	0	1 (2.1)	1 (1.1)
足根管症候群	1 (2.4)	0	1 (1.1)
Grade 3	1 (2.4)	0	1 (1.1)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject.
E/100PY = Events per 100 patient-years.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD + TCS (N=24) (PYS=42.3) Events (E/100PY)	UPA 30 mg QD + TCS (N=26) (PYS=47.5) Events (E/100PY)	Total (N=50) (PYS=89.8) Events (E/100PY)
精神障害	0	2 (4.2)	2 (2.2)
Grade 1	0	2 (4.2)	2 (2.2)
不眠症	0	2 (4.2)	2 (2.2)
Grade 1	0	2 (4.2)	2 (2.2)
生殖系および乳房障害	0	1 (2.1)	1 (1.1)
Grade 1	0	1 (2.1)	1 (1.1)
不正子宮出血	0	1 (2.1)	1 (1.1)
Grade 1	0	1 (2.1)	1 (1.1)
呼吸器、胸郭および縦隔障害	3 (7.1)	2 (4.2)	5 (5.6)
Grade 1	1 (2.4)	1 (2.1)	2 (2.2)
Grade 2	2 (4.7)	1 (2.1)	3 (3.3)
喘息	1 (2.4)	0	1 (1.1)
Grade 2	1 (2.4)	0	1 (1.1)
咳嗽	2 (4.7)	0	2 (2.2)
Grade 1	1 (2.4)	0	1 (1.1)
Grade 2	1 (2.4)	0	1 (1.1)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject.
E/100PY = Events per 100 patient-years.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD + TCS (N=24) (PYS=42.3) Events (E/100PY)	UPA 30 mg QD + TCS (N=26) (PYS=47.5) Events (E/100PY)	Total (N=50) (PYS=89.8) Events (E/100PY)
呼吸器、胸郭および縦隔障害 (Cont.)			
鼻出血	0	2 (4.2)	2 (2.2)
Grade 1	0	1 (2.1)	1 (1.1)
Grade 2	0	1 (2.1)	1 (1.1)
皮膚および皮下組織障害	21 (49.7)	15 (31.6)	36 (40.1)
Grade 1	13 (30.8)	9 (18.9)	22 (24.5)
Grade 2	8 (18.9)	6 (12.6)	14 (15.6)
ざ瘡	8 (18.9)	10 (21.0)	18 (20.0)
Grade 1	6 (14.2)	7 (14.7)	13 (14.5)
Grade 2	2 (4.7)	3 (6.3)	5 (5.6)
水疱	0	1 (2.1)	1 (1.1)
Grade 2	0	1 (2.1)	1 (1.1)
皮膚嚢腫	0	1 (2.1)	1 (1.1)
Grade 2	0	1 (2.1)	1 (1.1)
アレルギー性皮膚炎	0	1 (2.1)	1 (1.1)
Grade 2	0	1 (2.1)	1 (1.1)
アトピー性皮膚炎	5 (11.8)	1 (2.1)	6 (6.7)
Grade 1	3 (7.1)	1 (2.1)	4 (4.5)
Grade 2	2 (4.7)	0	2 (2.2)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject.
E/100PY = Events per 100 patient-years.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

MedDRA 22.1 System Organ Class Preferred Term Toxicity	UPA 15 mg QD + TCS (N=24) (PYS=42.3) Events (E/100PY)	UPA 30 mg QD + TCS (N=26) (PYS=47.5) Events (E/100PY)	Total (N=50) (PYS=89.8) Events (E/100PY)
皮膚および皮下組織障害 (Cont.)			
汗疹	3 (7.1)	0	3 (3.3)
Grade 1	3 (7.1)	0	3 (3.3)
口囲皮膚炎	1 (2.4)	0	1 (1.1)
Grade 2	1 (2.4)	0	1 (1.1)
皮膚腫瘤	1 (2.4)	0	1 (1.1)
Grade 2	1 (2.4)	0	1 (1.1)
皮膚潰瘍	1 (2.4)	0	1 (1.1)
Grade 2	1 (2.4)	0	1 (1.1)
蕁麻疹	2 (4.7)	1 (2.1)	3 (3.3)
Grade 1	1 (2.4)	1 (2.1)	2 (2.2)
Grade 2	1 (2.4)	0	1 (1.1)
血管障害	1 (2.4)	0	1 (1.1)
Grade 1	1 (2.4)	0	1 (1.1)
高血圧	1 (2.4)	0	1 (1.1)
Grade 1	1 (2.4)	0	1 (1.1)

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.
Table depicts maximum toxicity level adverse events for each preferred term as assessed for each subject.
E/100PY = Events per 100 patient-years.
Toxicity grading scale is based on NCI Common Terminology Criteria version 5.0.

相互参照：M16-047 試験 W52 Japan data Table 14.3 1.10.2 J

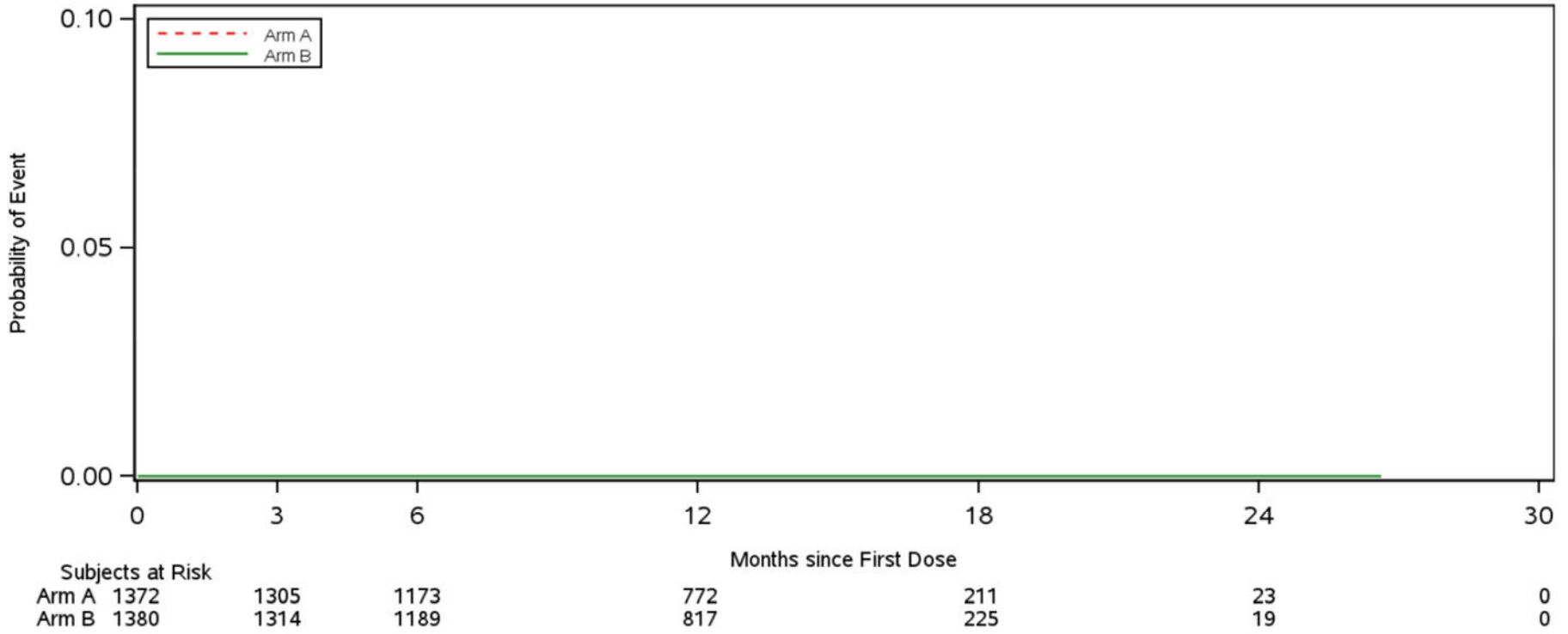
表 2.7.4.7-138.　投与 16 週時までの治験薬の投与中止に至った有害事象の集計表（Safety_DB_M 集団，日本人集団）：M16-047 試験

MedDRA 22.1 System Organ Class Preferred Term	Placebo + TCS (N=18) n (%)	Active UPA 15 mg QD + TCS (N=16) n (%)	Active UPA 30 mg QD + TCS (N=17) n (%)	Total (N=33) n (%)
Any adverse event	1 (5.6)	0	0	0
感染症および寄生虫症	1 (5.6)	0	0	0
心内膜炎	1 (5.6)	0	0	0

Note: Treatment-emergent adverse events in DB Period are defined as any adverse events with an onset or worsening date on or after the first dose of study drug and prior to the first dose of study drug in BE Period or no more than 30 days after the last dose of study drug in DB Period, whichever occurs firstly.
Subjects are counted once in each row, regardless of the number of events they may have had.

相互参照：M16-047 試験 W16 Japan data Table 14.3__2.3.1_J

図 2.7.4.7-1　長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の全体集団の死亡の Kaplan-Meier 曲線（更新時）

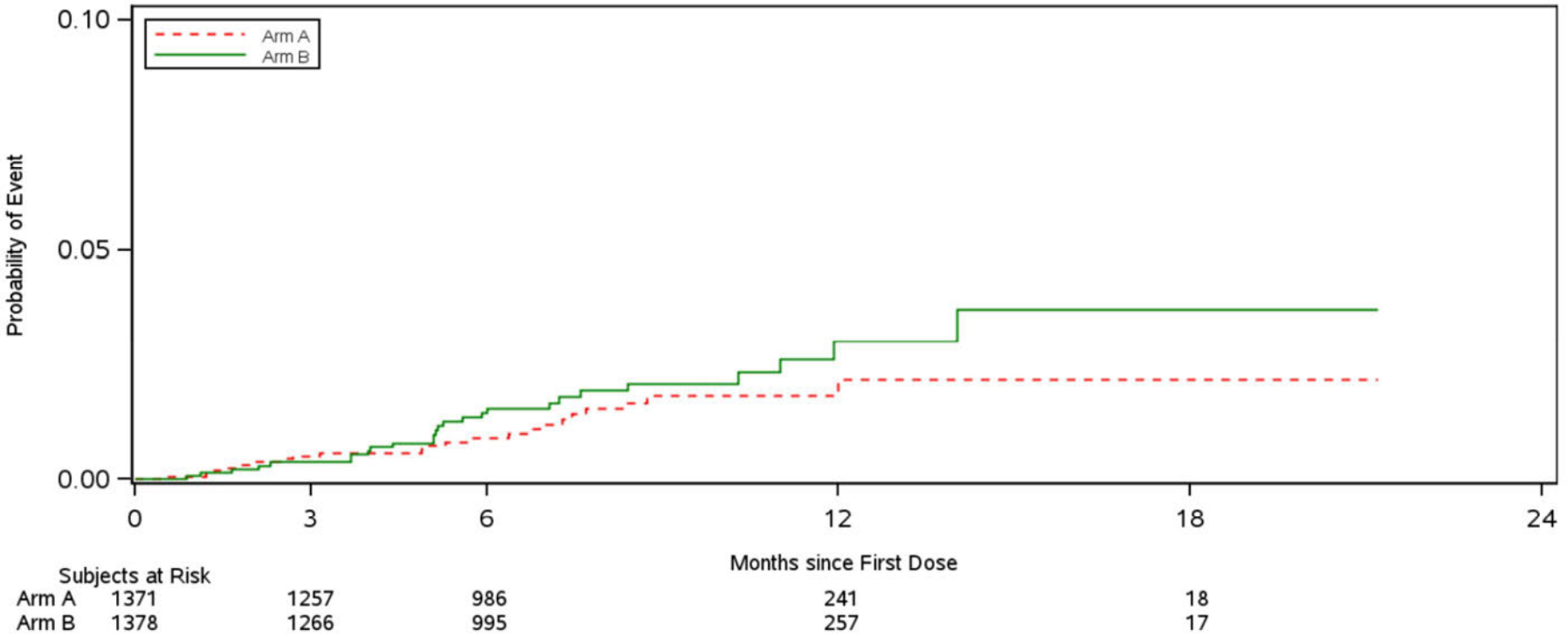


		Probability of Event (95% CI)					
	Events	Month 3	Month 6	Month 12	Month 18	Month 24	Month 30
Arm A (N = 1372)	0	- (- , -)	- (- , -)	- (- , -)	- (- , -)	- (- , -)	NA
Arm B (N = 1380)	1	0	0	0	<0.1%(0.0%, <0.1%)	<0.1%(0.0%, <0.1%)	NA

Arm A = Upadacitinib 15 mg QD, Arm B = Upadacitinib 30 mg QD, CI = confidence interval.

相互参照：Updated ISS Figure 2.4　2.4.5.8

図 2.7.4.7-2　長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の全体集団の重篤な感染症の Kaplan-Meier 曲線

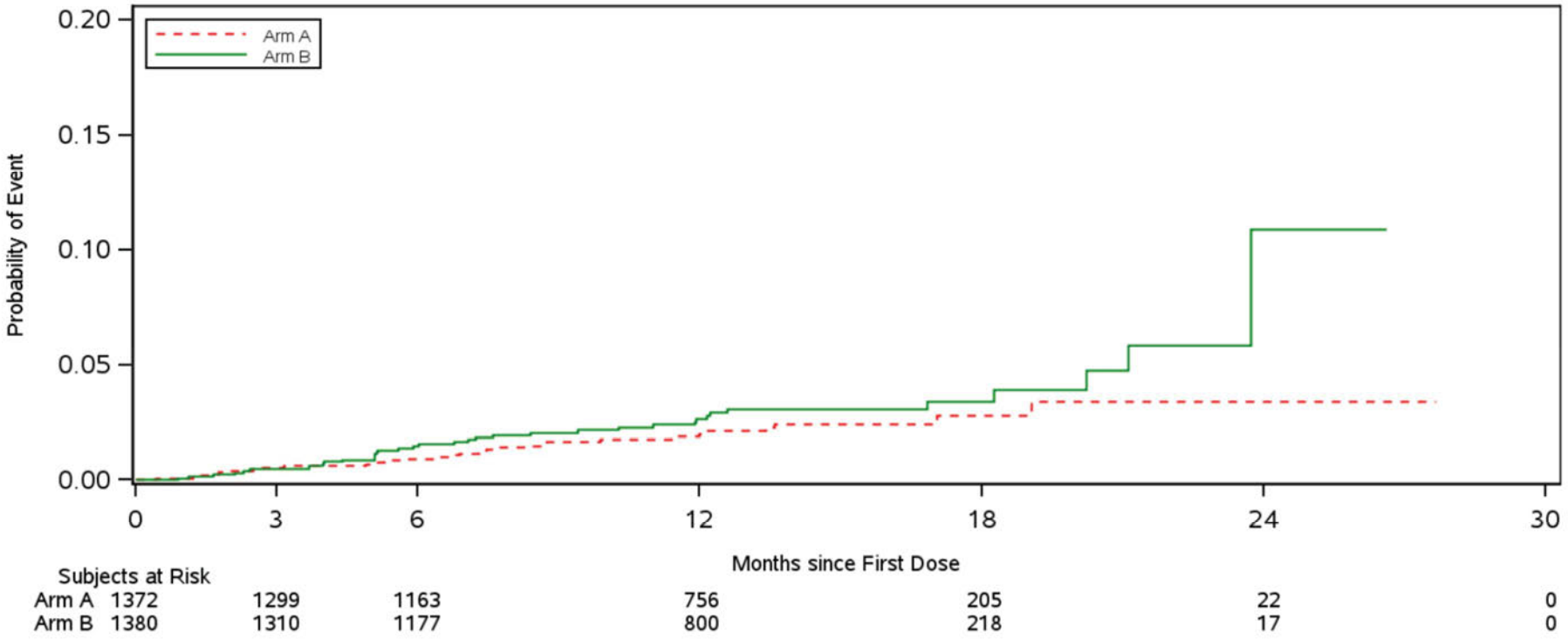


	Events	Probability of Event (95% CI)				
		Month 3	Month 6	Month 12	Month 18	Month 24
Arm A (N = 1371)	22	0.5%(0.0%, 1.0%)	0.9%(<0.1%, 1.7%)	1.8%(0.2%, 3.4%)	2.2%(0.2%, 4.1%)	NA
Arm B (N = 1378)	26	0.4%(0.0%, 0.8%)	1.4%(0.3%, 2.5%)	3.0%(0.6%, 5.3%)	3.7%(0.6%, 6.7%)	NA

Arm A = Upadacitinib 15 mg QD, Arm B = Upadacitinib 30 mg QD, CI = confidence interval.

相互参照：ISS Figure 2.4　2.4.5.1

図 2.7.4.7-3　長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の全体集団の重篤な感染症の Kaplan-Meier 曲線（更新時）

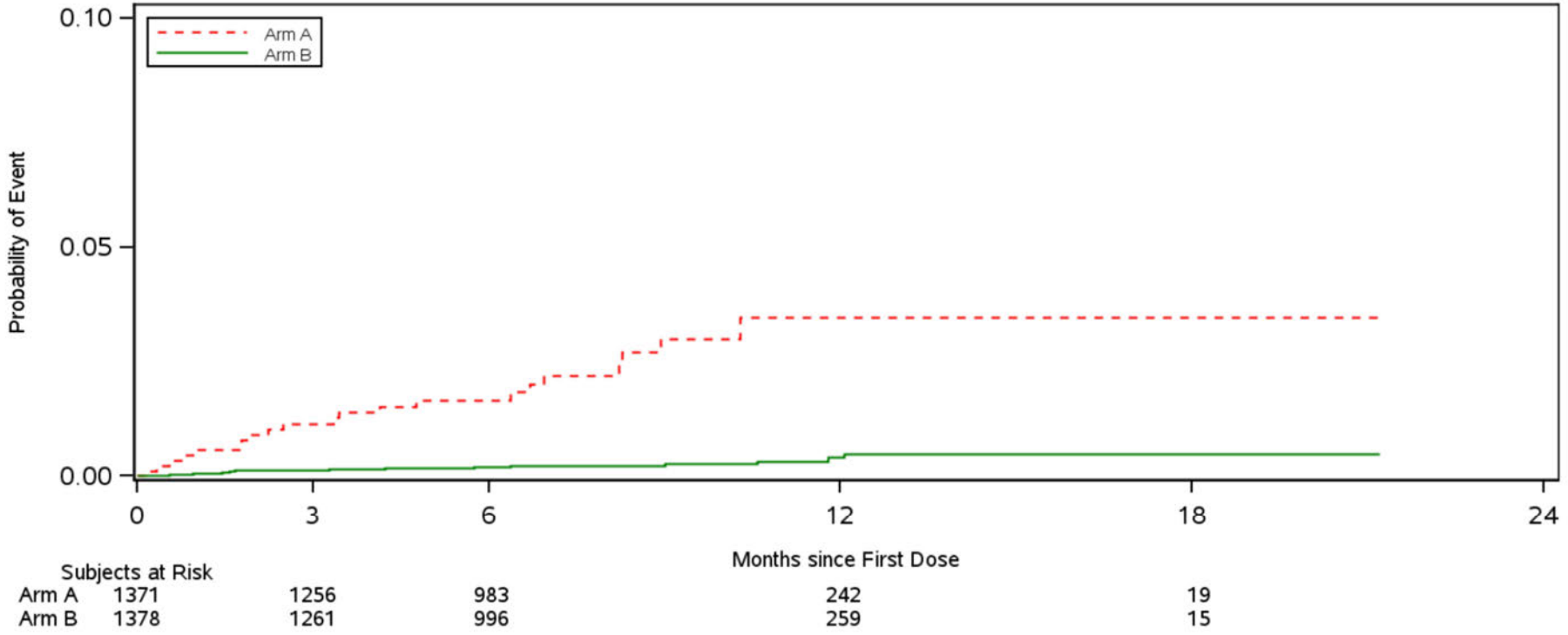


		Probability of Event (95% CI)					
	Events	Month 3	Month 6	Month 12	Month 18	Month 24	Month 30
Arm A (N = 1372)	30	0.5%(0.0%, 1.1%)	0.9%(<0.1%, 1.8%)	1.9%(0.2%, 3.5%)	2.8%(0.2%, 5.3%)	3.4%(0.0%, 6.7%)	NA
Arm B (N = 1380)	37	0.5%(<0.1%, 0.9%)	1.5%(0.3%, 2.6%)	2.6%(0.6%, 4.6%)	3.4%(0.7%, 6.0%)	10.9%(0.0%, 23.0%)	NA

Arm A = Upadacitinib 15 mg QD, Arm B = Upadacitinib 30 mg QD, CI = confidence interval.

相互参照：Updated ISS Figure 2.4　2.4.5.1

図 2.7.4.7-4　長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の全体集団の日和見感染の Kaplan-Meier 曲線

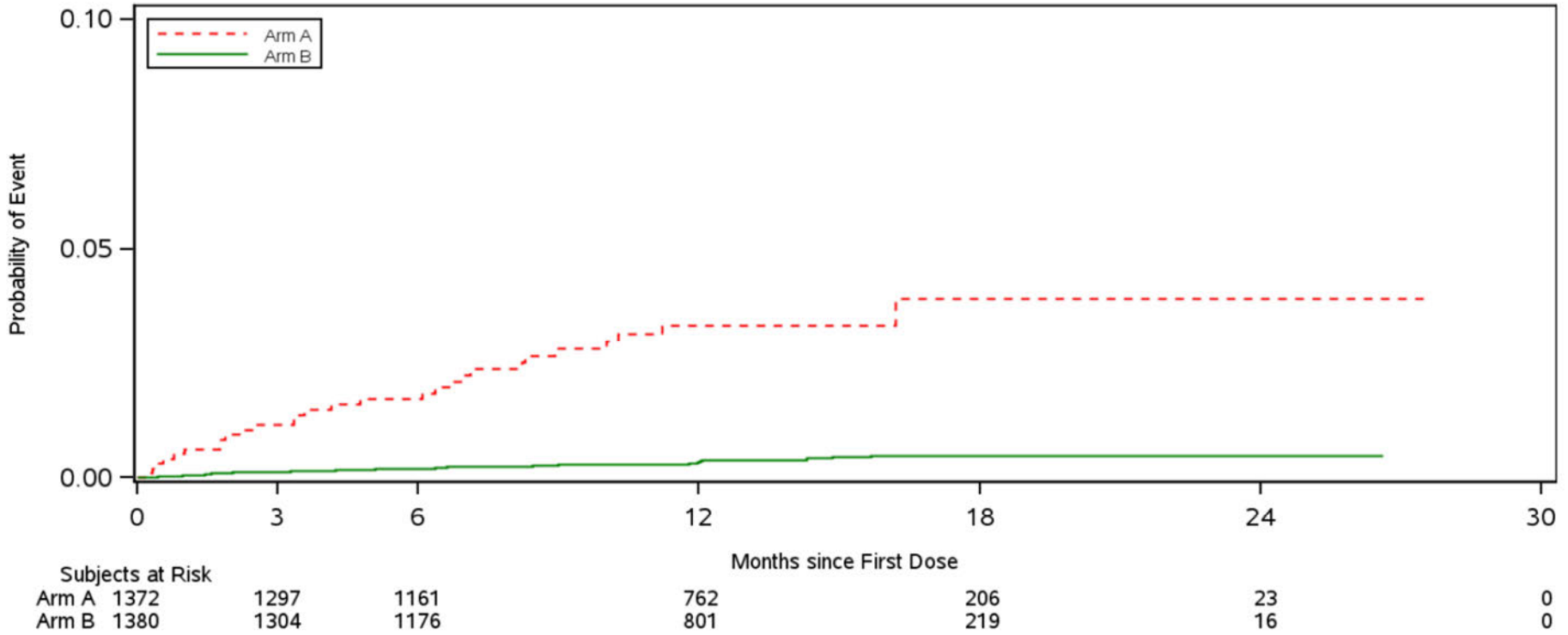


	Events	Probability of Event (95% CI) Month 3	Month 6	Month 12	Month 18	Month 24
Arm A (N = 1371)	21	1.1%(0.2%, 2.0%)	1.7%(0.5%, 2.8%)	3.5%(1.1%, 5.8%)	3.5%(1.1%, 5.8%)	NA
Arm B (N = 1378)	16	0.1%(0.0%, 0.4%)	0.2%(0.0%, 0.6%)	0.4%(0.0%, 1.2%)	0.5%(0.0%, 1.4%)	NA

Arm A = Upadacitinib 15 mg QD, Arm B = Upadacitinib 30 mg QD, CI = confidence interval.

相互参照：ISS Figure 2.4　2.4.5.2

図 2.7.4.7-5　長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の全体集団の日和見感染の Kaplan-Meier 曲線（更新時）

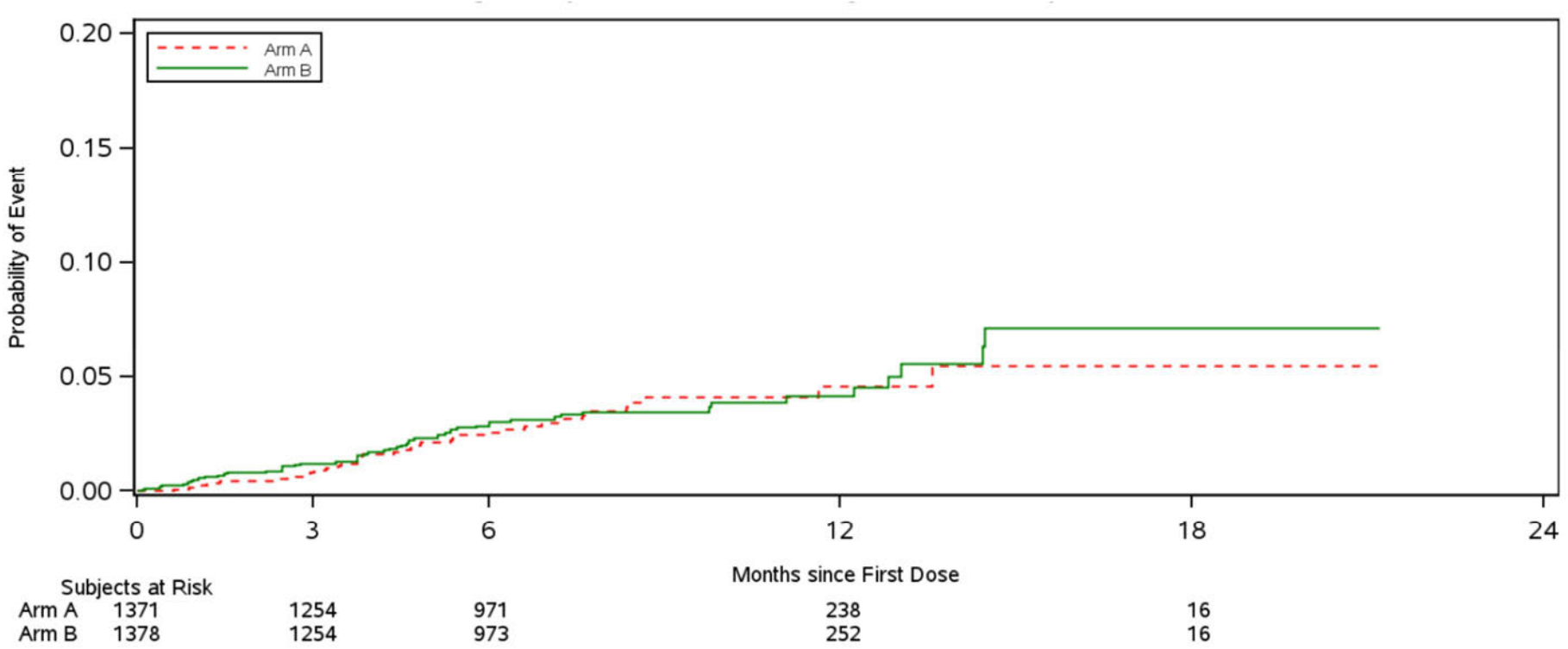


		Probability of Event (95% CI)					
	Events	Month 3	Month 6	Month 12	Month 18	Month 24	Month 30
Arm A (N = 1372)	28	1.2%(0.3%, 2.0%)	1.7%(0.5%, 2.9%)	3.3%(1.1%, 5.5%)	3.9%(1.0%, 6.7%)	3.9%(1.0%, 6.7%)	NA
Arm B (N = 1380)	29	0.1%(0.0%, 0.4%)	0.2%(0.0%, 0.6%)	0.3%(0.0%, 1.0%)	0.5%(0.0%, 1.4%)	0.5%(0.0%, 1.4%)	NA

Arm A = Upadacitinib 15 mg QD, Arm B = Upadacitinib 30 mg QD, CI = confidence interval.

相互参照：Updated ISS Figure 2.4　2.4.5.2

図 2.7.4.7-6　長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の全体集団の帯状疱疹の Kaplan-Meier 曲線

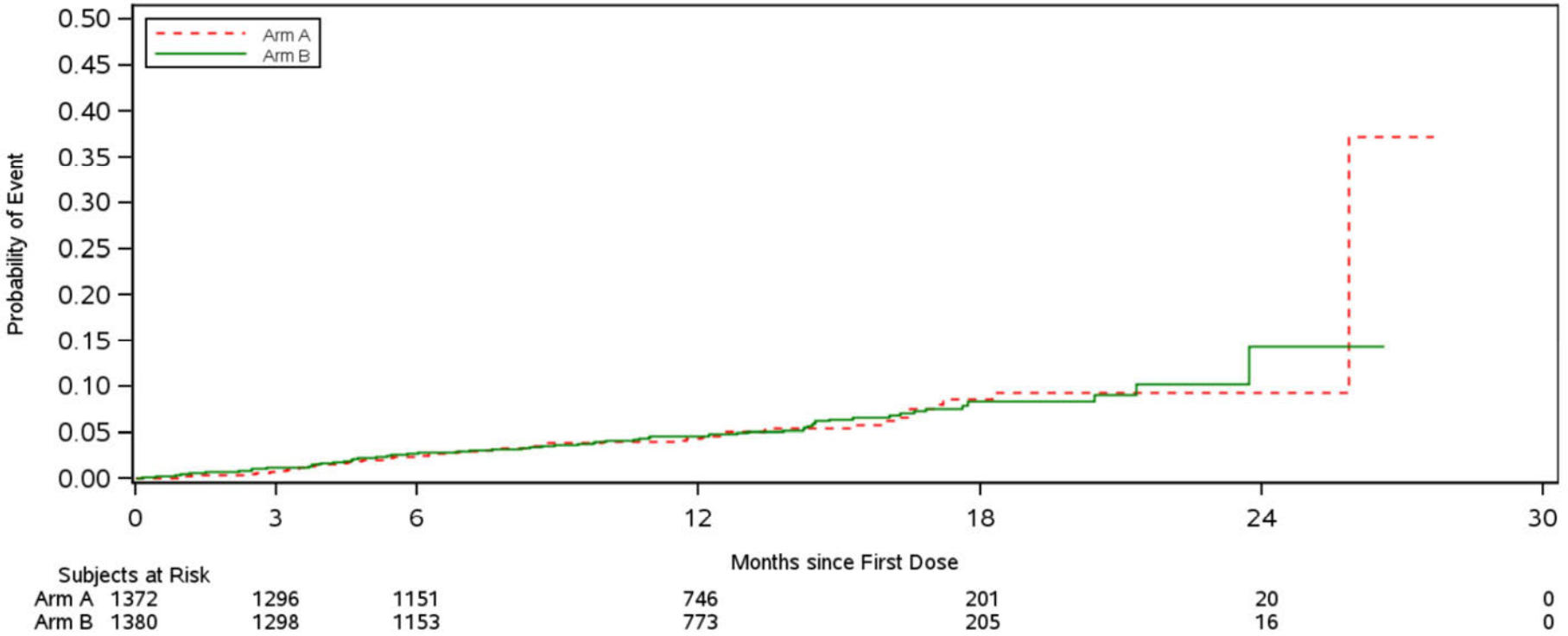


	Events	Probability of Event (95% CI) Month 3	Month 6	Month 12	Month 18	Month 24
Arm A (N = 1371)	37	0.8%(0.2%, 1.5%)	2.6%(1.0%, 4.1%)	4.5%(1.8%, 7.2%)	5.4%(1.9%, 8.9%)	NA
Arm B (N = 1378)	55	1.2%(0.4%, 2.0%)	2.8%(1.3%, 4.4%)	4.1%(1.8%, 6.4%)	7.1%(2.5%, 11.6%)	NA

Arm A = Upadacitinib 15 mg QD, Arm B = Upadacitinib 30 mg QD, CI = confidence interval.

相互参照：ISS Figure 2.4　2.4.5.5

図 2.7.4.7-7　長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の全体集団の帯状疱疹の Kaplan-Meier 曲線（更新時）

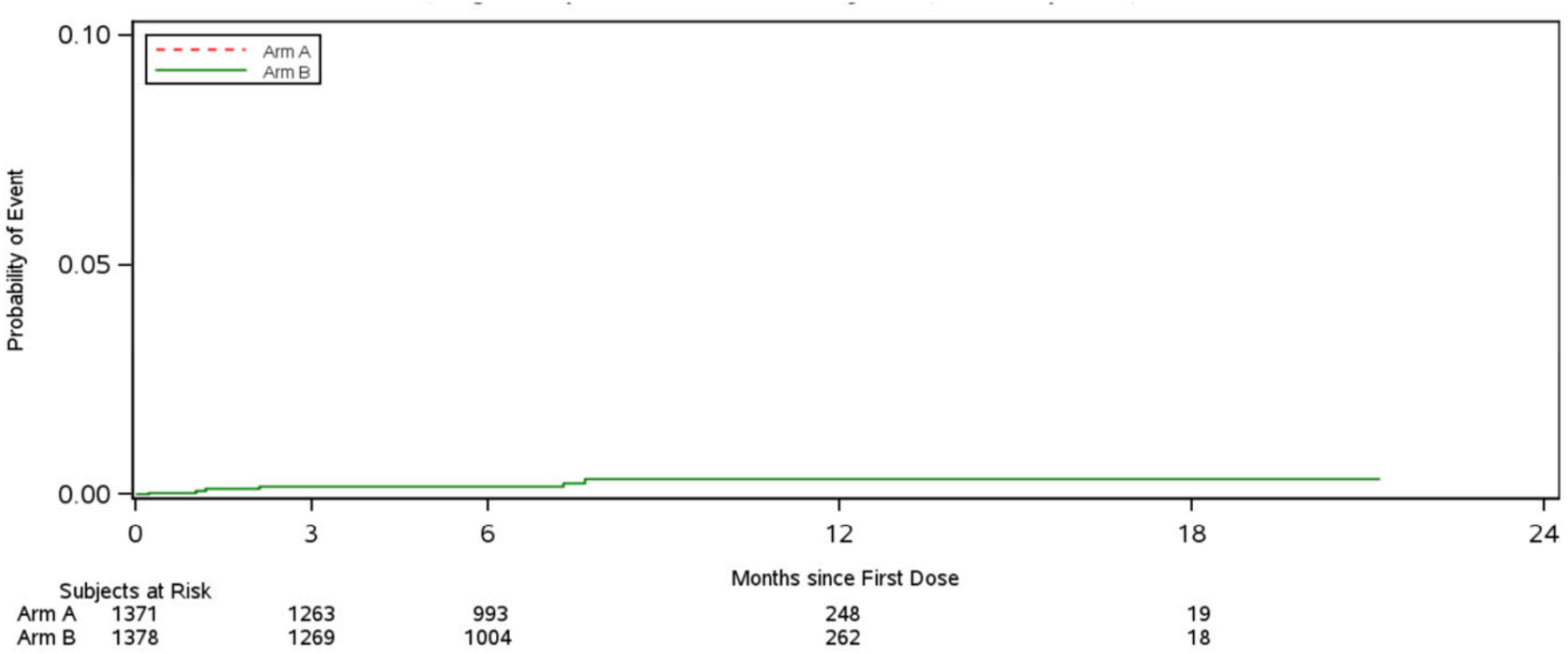


	Events	Probability of Event (95% CI)					
		Month 3	Month 6	Month 12	Month 18	Month 24	Month 30
Arm A (N = 1372)	56	0.8%(0.2%, 1.5%)	2.5%(1.0%, 3.9%)	4.3%(1.8%, 6.7%)	8.5%(3.0%, 13.8%)	9.2%(3.1%, 14.9%)	NA
Arm B (N = 1380)	88	1.2%(0.4%, 1.9%)	2.7%(1.2%, 4.2%)	4.7%(2.1%, 7.1%)	8.3%(3.4%, 12.9%)	14.3%(2.2%, 24.9%)	NA

Arm A = Upadacitinib 15 mg QD, Arm B = Upadacitinib 30 mg QD, CI = confidence interval.

相互参照：Updated ISS Figure 2.4　2.4.5.5

図 2.7.4.7-8　長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の全体集団の非黒色腫皮膚癌を除く悪性腫瘍の Kaplan-Meier 曲線

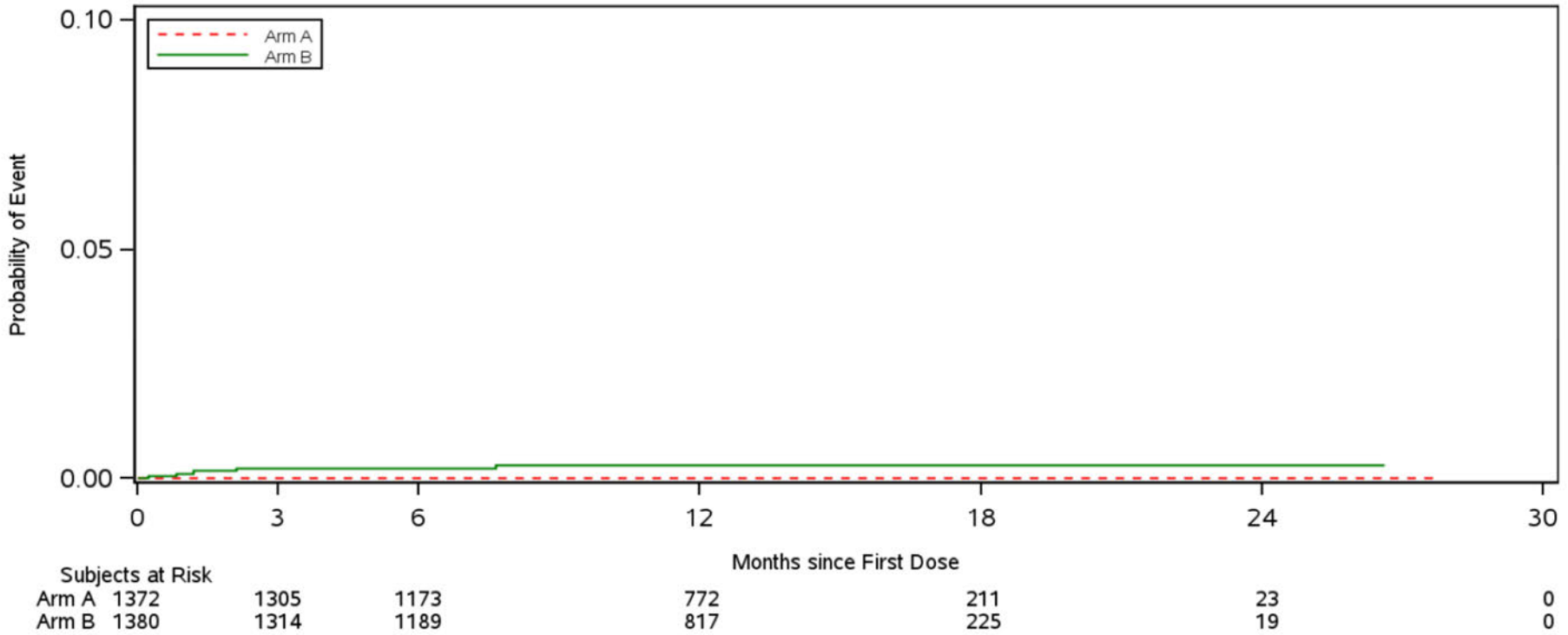


	Events	Probability of Event (95% CI) Month 3	Month 6	Month 12	Month 18	Month 24
Arm A (N = 1371)	0	- (- , -)	- (- , -)	- (- , -)	- (- , -)	NA
Arm B (N = 1378)	6	0.2%(0.0%, 0.5%)	0.2%(0.0%, 0.5%)	0.3%(0.0%, 1.0%)	0.3%(0.0%, 1.0%)	NA

Arm A = Upadacitinib 15 mg QD, Arm B = Upadacitinib 30 mg QD, CI = confidence interval.

相互参照：ISS Figure 2.4__2.4.5.3

図 2.7.4.7-9　長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の全体集団の非黒色腫皮膚癌を除く悪性腫瘍の Kaplan-Meier 曲線（更新時）

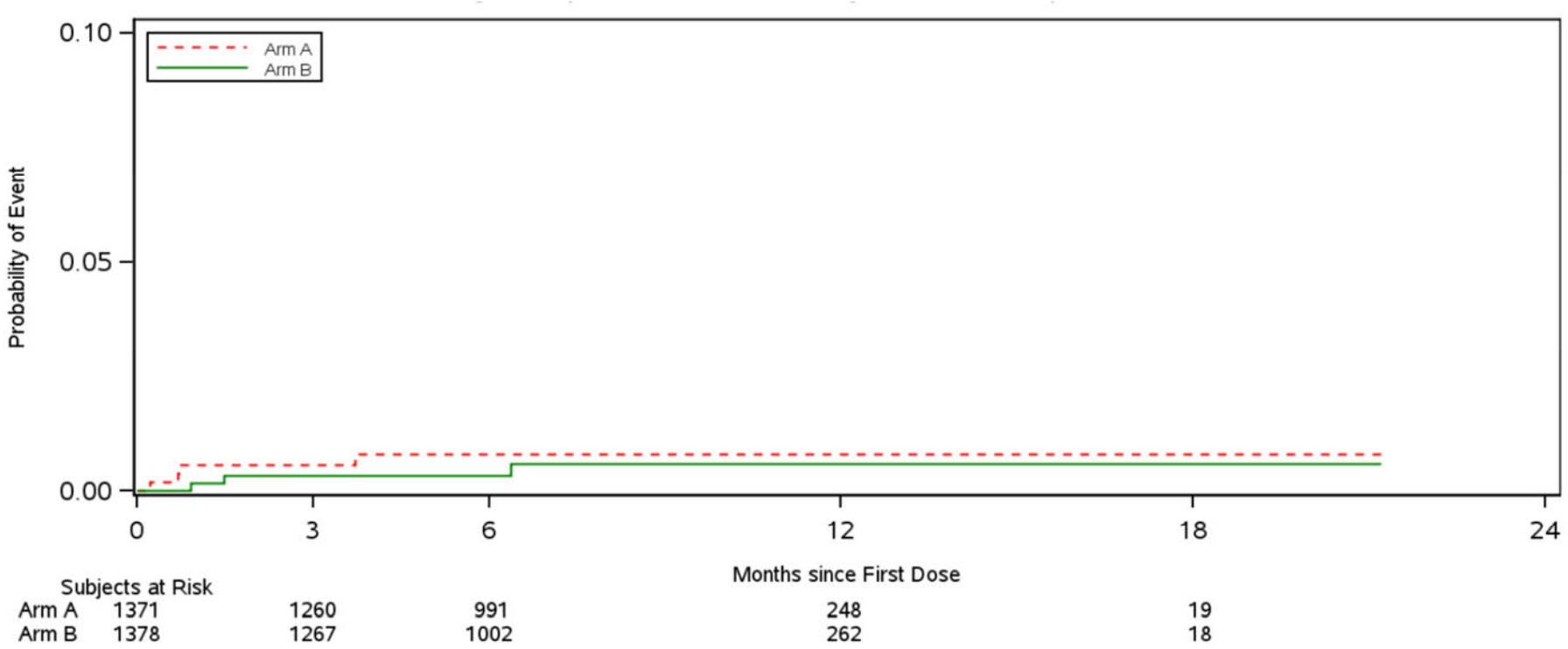


	Events	Probability of Event (95% CI)					
		Month 3	Month 6	Month 12	Month 18	Month 24	Month 30
Arm A (N = 1372)	2	0	0	<0.1%(0.0%, <0.1%)	<0.1%(0.0%, <0.1%)	<0.1%(0.0%, <0.1%)	NA
Arm B (N = 1380)	5	0.2%(0.0%, 0.7%)	0.2%(0.0%, 0.7%)	0.3%(0.0%, 0.9%)	0.3%(0.0%, 0.9%)	0.3%(0.0%, 0.9%)	NA

Arm A = Upadacitinib 15 mg QD, Arm B = Upadacitinib 30 mg QD, CI = confidence interval.

相互参照：Updated ISS Figure 2.4　2.4.5.3

図 2.7.4.7-10　長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の全体集団の非黒色腫皮膚癌の Kaplan-Meier 曲線

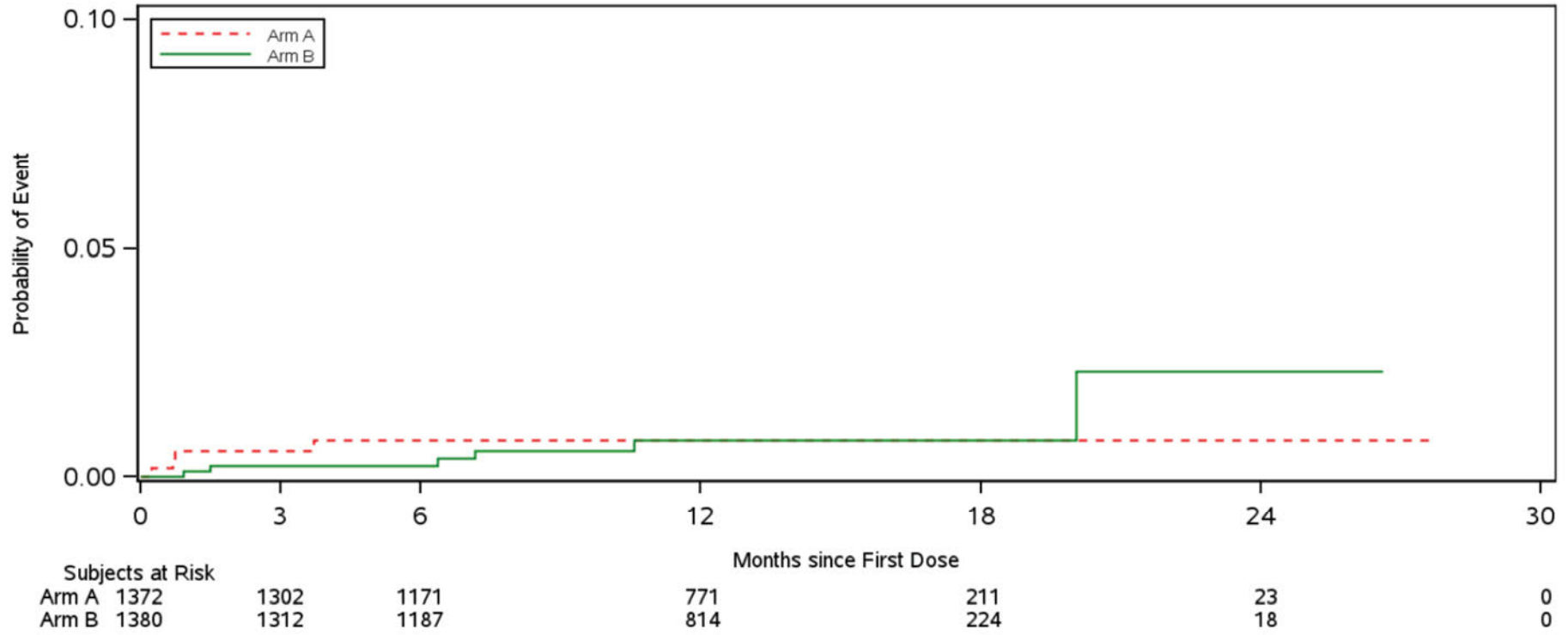


	Events	Probability of Event (95% CI)				
		Month 3	Month 6	Month 12	Month 18	Month 24
Arm A (N = 1371)	4	0.6%(0.0%, 1.3%)	0.8%(0.0%, 1.7%)	0.8%(0.0%, 1.7%)	0.8%(0.0%, 1.7%)	NA
Arm B (N = 1378)	3	0.3%(0.0%, 0.9%)	0.3%(0.0%, 0.9%)	0.6%(0.0%, 1.4%)	0.6%(0.0%, 1.4%)	NA

Arm A = Upadacitinib 15 mg QD, Arm B = Upadacitinib 30 mg QD, CI = confidence interval.

相互参照：ISS Figure 2.4　2.4.5.4

図 2.7.4.7-11　長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の全体集団の非黒色腫皮膚癌の Kaplan-Meier 曲線（更新時）

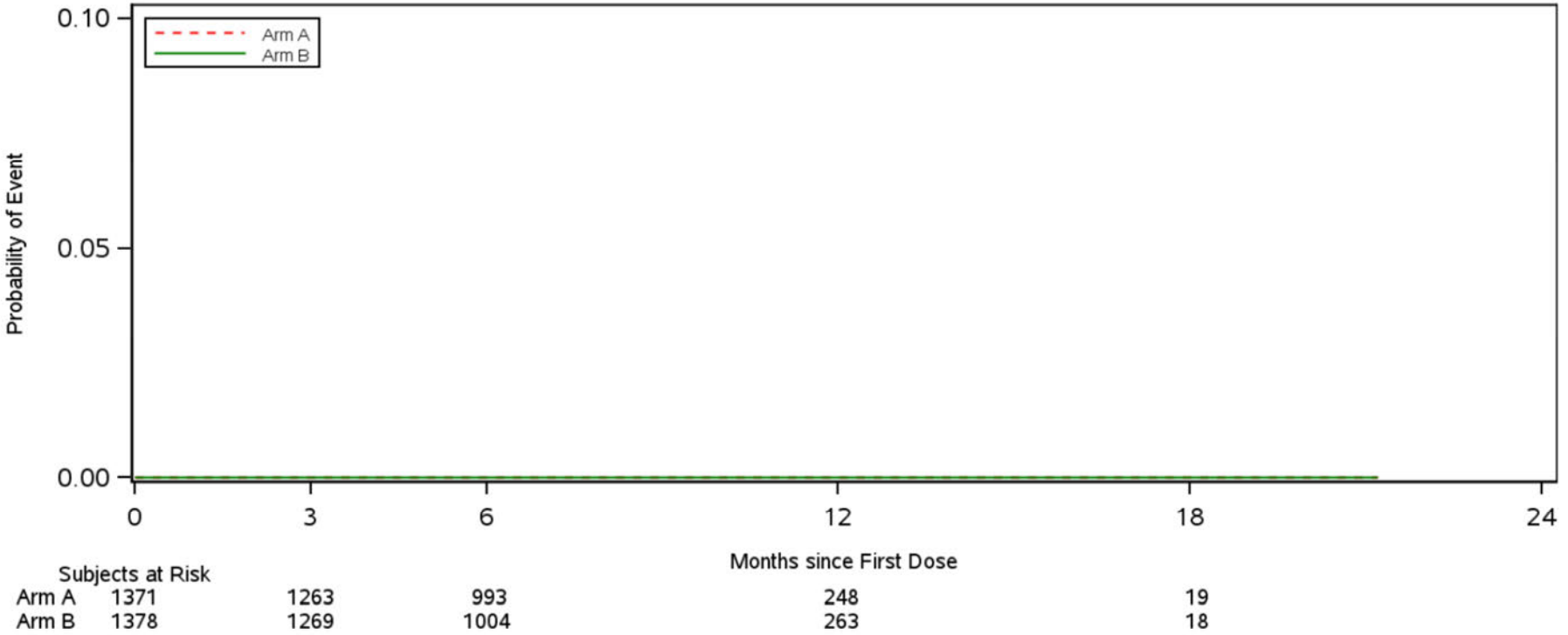


		Probability of Event (95% CI)					
	Events	Month 3	Month 6	Month 12	Month 18	Month 24	Month 30
Arm A (N = 1372)	4	0.6%(0.0%, 1.3%)	0.8%(0.0%, 1.7%)	0.8%(0.0%, 1.7%)	0.8%(0.0%, 1.7%)	0.8%(0.0%, 1.7%)	NA
Arm B (N = 1380)	6	0.3%(0.0%, 0.7%)	0.3%(0.0%, 0.7%)	0.8%(0.0%, 2.0%)	0.8%(0.0%, 2.0%)	2.3%(0.0%, 6.9%)	NA

Arm A = Upadacitinib 15 mg QD, Arm B = Upadacitinib 30 mg QD, CI = confidence interval.

相互参照：Updated ISS Figure 2.4__2.4.5.4

図 2.7.4.7-12　長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の全体集団の主要心血管事象の Kaplan-Meier 曲線

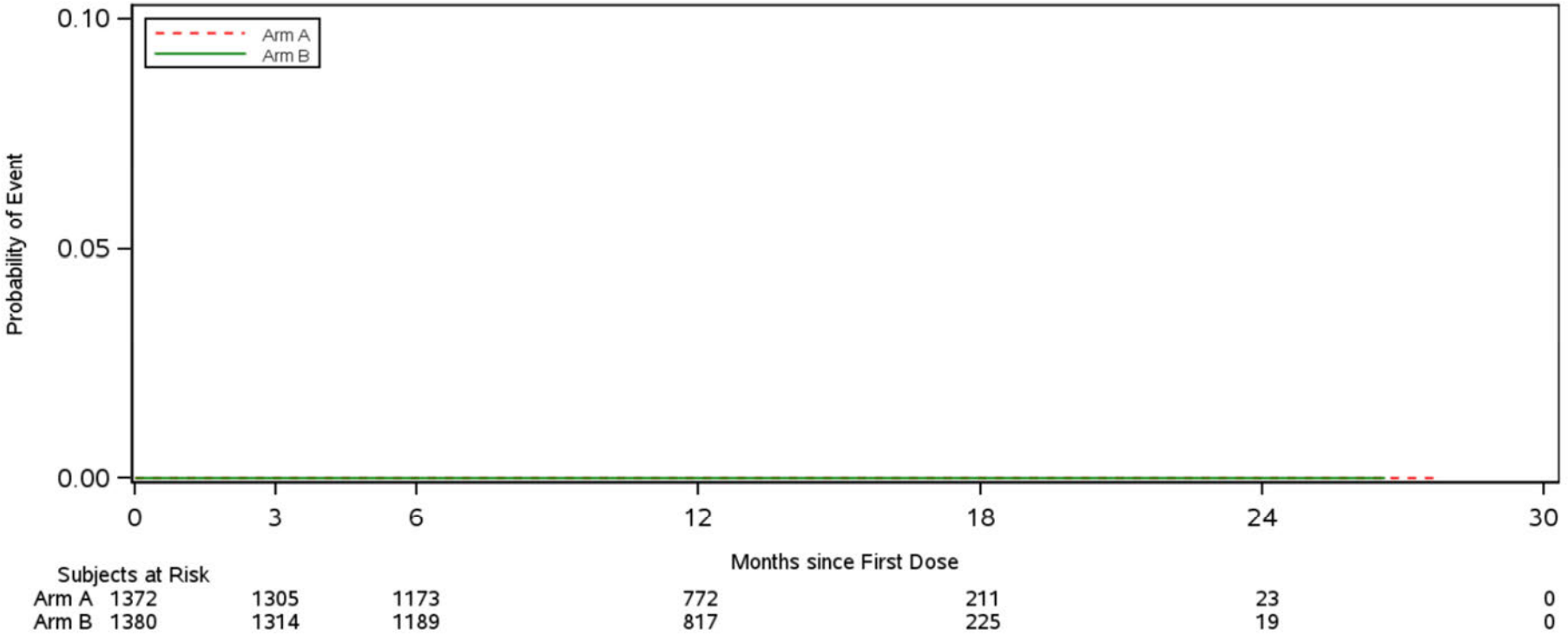


	Events	Probability of Event (95% CI)				
		Month 3	Month 6	Month 12	Month 18	Month 24
Arm A (N = 1371)	2	<0.1%(0.0%, <0.1%)	<0.1%(0.0%, <0.1%)	<0.1%(0.0%, <0.1%)	<0.1%(0.0%, <0.1%)	NA
Arm B (N = 1378)	1	0	0	<0.1%(0.0%, <0.1%)	<0.1%(0.0%, <0.1%)	NA

Arm A = Upadacitinib 15 mg QD, Arm B = Upadacitinib 30 mg QD, CI = confidence interval.

相互参照：ISS Figure 2.4　2.4.5.6

図 2.7.4.7-13　長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の全体集団の主要心血管事象の Kaplan-Meier 曲線（更新時）

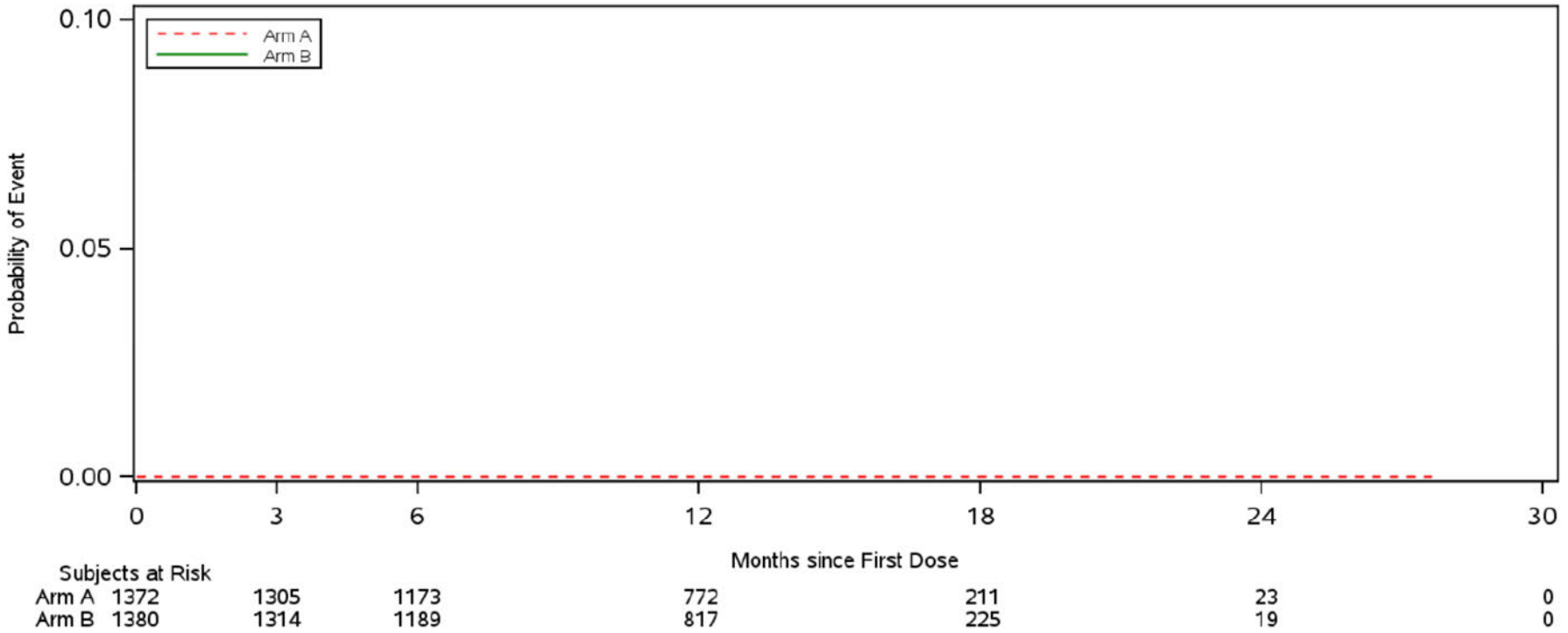


		Probability of Event (95% CI)					
	Events	Month 3	Month 6	Month 12	Month 18	Month 24	Month 30
Arm A (N = 1372)	3	<0.1%(0.0%, <0.1%)	<0.1%(0.0%, <0.1%)	<0.1%(0.0%, <0.1%)	<0.1%(0.0%, <0.1%)	<0.1%(0.0%, <0.1%)	NA
Arm B (N = 1380)	1	0	0	<0.1%(0.0%, <0.1%)	<0.1%(0.0%, <0.1%)	<0.1%(0.0%, <0.1%)	NA

Arm A = Upadacitinib 15 mg QD, Arm B = Upadacitinib 30 mg QD, CI = confidence interval.

相互参照：Updated ISS Figure 2.4　2.4.5.6

図 2.7.4.7-14　長期第 III 相ウパダシチニブ併合解析集団（長期，M16-045 試験，M16-047 試験，M17-377 試験及び M18-891 試験）の全体集団の血栓症の Kaplan-Meier 曲線（更新時）



	Events	Probability of Event (95% CI) Month 3	Month 6	Month 12	Month 18	Month 24	Month 30
Arm A (N = 1372)	2	0	0	<0.1%(0.0%, <0.1%)	<0.1%(0.0%, <0.1%)	<0.1%(0.0%, <0.1%)	NA
Arm B (N = 1380)	0	- (- , -)	- (- , -)	- (- , -)	- (- , -)	- (- , -)	NA

Arm A = Upadacitinib 15 mg QD, Arm B = Upadacitinib 30 mg QD, CI = confidence interval.

相互参照：Updated ISS Figure 2.4　2.4.5.7

2.7.5 参考文献

参考文献は，各セクションの末尾に記載した。

M20-017 試験

治験の標題：高脂肪/高カロリー食摂取後及び絶食下において，ウパダシチニブの第 III 相試験で使用した湿式造粒製剤に対する市販予定製剤のバイオアベイラビリティを評価する第 I 相試験	
施設数 / 実施国名： 2 施設 / 米国	
治験責任医師： [redacted], MD	
公表文献 (参考資料) ： なし	
治験期間： 最初の被験者の初回来院日：20[redacted] 年 [redacted] 月 [redacted] 日 最後の被験者の最終来院日：20[redacted] 年 [redacted] 月 [redacted] 日	開発のフェーズ：I
目的： パート 1：高脂肪/高カロリー食摂取後及び絶食下において，ウパダシチニブの市販予定製剤（15 mg）のバイオアベイラビリティを臨床試験用製剤（15 mg）と比較して評価する。 パート 2：高脂肪/高カロリー食摂取後及び絶食下において，ウパダシチニブの市販予定製剤（30 mg）のバイオアベイラビリティを臨床試験用製剤（30 mg）と比較して評価する。	
被験者数 (計画時と解析時) ： 計画時：80 名，解析時 80 名	
診断と主要な組入れ基準： スクリーニングの時点で 18 歳から 55 歳の健康な男女	
治験方法： 単回投与，非盲検，無作為化，4 期，4 順序，2 パートのクロスオーバー試験を実施した。各期の投与後 72 時間まで，ウパダシチニブの濃度測定用の血液試料を採取した。	
被験薬，用量，投与方法及びバッチ番号： ウパダシチニブの臨床試験用 15 mg 錠（ER17Y）：バルクロット番号 [redacted] ウパダシチニブの市販予定 15 mg 錠（ER17）：バルクロット番号 [redacted] ウパダシチニブの臨床試験用 30 mg 錠（ER18Y）：バルクロット番号 [redacted] ウパダシチニブの市販予定 30 mg 錠（ER18）：バルクロット番号 [redacted] パート 1 では 15 mg，パート 2 では 30 mg の用量で経口投与した。 治療期間： パート 1：4 日間の間隔をあけてウパダシチニブ 15 mg を 4 回単回投与 パート 2：4 日間の間隔をあけてウパダシチニブ 30 mg を 4 回単回投与	
対照薬，用量，投与方法及びバッチ番号： 該当なし	
評価基準： 薬物動態： C_{max}，T_{max}，$t_{1/2}$，AUC_t，AUC_{inf}，AUC_{0-12}，AUC_{12-t}	
統計手法：	

薬物動態：

各パートにおいて，C_{max}，AUC_t，AUC_{inf}，AUC_{0-12}，AUC_{12-t}の自然対数変換値について線形混合効果解析を実施した。混合モデリングでは，それぞれの試験レジメンを対応する標準レジメンと比較した。

各パートにおいて，C_{max}，AUC_t，AUC_{inf}，AUC_{0-12}，AUC_{12-t}の自然対数変換値を解析することにより，標準レジメンに対する試験レジメンのバイオアベイラビリティ，すなわち市販予定製剤に対する高脂肪/高カロリー食後又は絶食下での臨床試験製剤のバイオアベイラビリティの点推定値及びその90%信頼区間を評価した。

要約/結論

薬物動態の結果：

絶食下及び高脂肪/高カロリー食摂取後におけるウパダシチニブ15 mg製剤のバイオアベイラビリティの点推定値及び90%信頼区間

レジメン	薬物動態パラメータ	中心値		相対バイオアベイラビリティ	
試験 vs.標準	（単位）	試験	標準	点推定値	90%信頼区間
B vs. A	C_{max}（ng/mL）	29.1	28.1	1.038	0.936 - 1.150
	AUC_t（ng•h/mL）	250	256	0.973	0.919 - 1.031
	AUC_{inf}（ng•h/mL）	254	265	0.960	0.907 - 1.015
	AUC_{0-12}（ng•h/mL）	184	184	1.003	0.938 - 1.072
	AUC_{12-t}（ng•h/mL）	62.7	70.3	0.892	0.823 - 0.968
D vs. C	C_{max}（ng/mL）	47.4	48.4	0.980	0.915 - 1.049
	AUC_t（ng•h/mL）	318	335	0.949	0.906 - 0.994
	AUC_{inf}（ng•h/mL）	323	339	0.952	0.910 - 0.997
	AUC_{0-12}（ng•h/mL）	267	281	0.949	0.897 - 1.004
	AUC_{12-t}（ng•h/mL）	49.1	51.4	0.956	0.882 - 1.036

レジメンA：絶食下で臨床試験製剤（ER17Y）15 mgを単回投与（レジメンBに対する標準レジメン）

レジメンB：絶食下で市販予定製剤（ER17）15 mgを単回投与（レジメンAに対する試験レジメン）

レジメンC：高脂肪/高カロリー食後に臨床試験製剤（ER17Y）15 mgを単回投与（レジメンDに対する標準レジメン）

レジメンD：高脂肪/高カロリー食後に市販予定製剤（ER17）15 mgを単回投与（レジメンCに対する試験レジメン）

絶食下及び高脂肪/高カロリー食摂取後におけるウパダシチニブ30 mg製剤のバイオアベイラビリティの点推定値及び90%信頼区間

レジメン	薬物動態パラメータ	中心値		相対バイオアベイラビリティ	
試験 vs.標準	（単位）	試験	標準	点推定値	90%信頼区間
F vs. E	C_{max}（ng/mL）	69.4	62.1	1.117	1.042 - 1.197
	AUC_t（ng•h/mL）	513	499	1.029	0.971 - 1.091
	AUC_{inf}（ng•h/mL）	524	509	1.029	0.971 - 1.091
	AUC_{0-12}（ng•h/mL）	394	369	1.069	0.995 - 1.149
	AUC_{12-t}（ng•h/mL）	113	121	0.931	0.837 - 1.036
H vs. G	C_{max}（ng/mL）	94.7	94.9	0.998	0.930 - 1.070

AUC_t（ng•h/mL）	622	627	0.992	0.952 - 1.032
AUC_{inf}（ng•h/mL）	630	634	0.994	0.954 - 1.035
AUC_{0-12}（ng•h/mL）	511	514	0.993	0.946 - 1.043
AUC_{12-t}（ng•h/mL）	106	107	0.986	0.915 - 1.063

レジメン E：絶食下で臨床試験製剤（ER18Y）30 mg を単回投与（レジメン F に対する標準レジメン）

レジメン F：絶食下で市販予定製剤（ER18）30 mg を単回投与（レジメン E に対する試験レジメン）

レジメン G：高脂肪/高カロリー食後に臨床試験製剤（ER18Y）30 mg を単回投与（レジメン H に対する標準レジメン）

レジメン H：高脂肪/高カロリー食後に市販予定製剤（ER18）30 mg を単回投与（レジメン G に対する試験レジメン）

安全性の結果：

検討したレジメンの忍容性はおおむね良好であった。1 名が高度の胆石症のため試験を中止したが，本事象は治験責任医師によって治験薬と関連なしと評価された。試験期間中に臨床的に重要なバイタルサイン及び臨床検査値異常は認められなかった。報告された有害事象に特定のパターンはなく，本試験において新たな安全性の問題は認められなかった。

結論:

15 mg 含量の市販予定製剤（ER17）は，絶食下及び高脂肪/高カロリー食摂取後において 15 mg 含量の臨床試験用製剤（ER17Y）と生物学的に同等である。30 mg 含量の市販予定製剤（ER18）は，絶食条件下及び高脂肪/高カロリー食摂取後において 30 mg 含量の臨床試験用製剤（ER18Y）と生物学的に同等である。

M16-048 試験

治験の標題： 中等症から重症の成人アトピー性皮膚炎患者におけるウパダシチニブの第 IIb 相，多施設共同，ランダム化，プラセボ対照，二重盲検，用量設定試験	
治験実施施設： 8 ヵ国（オーストラリア，カナダ，フィンランド，ドイツ，日本，オランダ，スペイン及びアメリカ合衆国）の 36 施設	
治験調整医師： [redacted], MD, PhD	
公表文献（参考資料）： 6 抄録	
試験期間（年数）： 最初の被験者の初回来院日：2016 年 10 月 25 日 最後の被験者の最終来院日：2019 年 1 月 31 日	開発のフェーズ：IIb
目的： 中等症から重症の成人アトピー性皮膚炎患者の治療におけるウパダシチニブ単剤の反復投与の安全性及び有効性をプラセボと比較する。	
被験者数（計画時と解析時）： 計画時：約 160 名，解析時：167 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）18 歳以上 75 歳以下の成人男性及び女性，2）皮膚科医よりアトピー性皮膚炎と確定診断され（Hanifin & Rajka の診断基準に基づく），かつベースラインの 1 年以上前に発症している，3）湿疹面積・重症度指数（以下「EASI」）スコア 16 以上，体表面積 10%以上，及び治験責任医師による包括的評価（以下「IGA」）スコア 3 以上と定義される中等症から重症のアトピー性皮膚炎を有する，4）副腎皮質ステロイド外用薬若しくはカルシニューリン阻害外用薬で効果不十分，又は外用療法が医学的に推奨できない（例：重大な副作用又は安全性上のリスクのため）であることを示す記録がある，5）ベースライン前の少なくとも 7 日間，無添加かつ無刺激のエモリエント剤を 1 日 2 回使用している。 主要な除外基準は以下のとおりであった。 1）ヤヌスキナーゼ阻害剤の使用経験がある，2）ベースライン前の 10 日以内に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，処方された保湿剤又はセラミド，ヒアルロン酸，尿素若しくはフィラグリンを添加された保湿剤による治療を受けている，3）デュピルマブの使用経験がある，4）ベースライン前の 4 週間以内にアトピー性皮膚炎に対する全身療法（副腎皮質ステロイド，メトトレキサート，シクロスポリン，アザチオプリン，ホスホジエステラーゼ 4 型阻害剤及びミコフェノール酸モフェチルなど）を受けている，5）スクリーニング期間中に，以下の臨床検査値を認めた：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（4 変数を用いた Modification of Diet in Renal Disease 簡易式に基づく），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： 本試験は中等症から重症の成人アトピー性皮膚炎患者を対象として，ウパダシチニブの安全性及び有効性を評価する 88 週間，第 IIb 相，ランダム化，二重盲検，並行群間，プラセボ対照，多施設共同試験であった。 本試験は，その科学的な目的及び規制要件に適合するため，約 160 名の患者を登録するように計画され，倫理的	

な観点から不必要に多くの患者を組み入れなかった。そのため，目標被験者数の組入れを達成した場合は，スクリーニング中の被験者であっても，本試験に組み入れない可能性があった。 本試験は，最長 35 日間のスクリーニング期間，16 週間の二重盲検投与期間（第 1 ピリオド）及び 72 週間の二重盲検投与期間（第 2 ピリオド）で構成され，治験薬投与期間は 88 週間とした。また，有害事象若しくは重篤な有害事象の持続状況，又は新たな有害事象若しくは重篤な有害事象の発現を確認するために，治験薬の最終投与から約 30 日後に追跡調査来院（来院できない場合は電話確認）を行った。 適格性基準を満たした被験者を，4 つの治験薬投与群のいずれかに 1:1:1:1 の割合でランダム化した。第 1 ピリオドを完了した被験者は，投与 16 週時に 72 週間のプラセボ対照二重盲検投与期間（第 2 ピリオド）に移行し，1:1 の割合で再度割り付けられた。 グループ 1：ウパダシチニブ 7.5 mg 1 日 1 回（以下「QD」）（投与 1 日目～投与 16 週時）→ウパダシチニブ 7.5 mg QD 又はプラセボ（投与 16 週時以降） グループ 2：ウパダシチニブ 15 mg QD（投与 1 日目～投与 16 週時）→ ウパダシチニブ 15 mg QD 又はプラセボ（投与 16 週時以降） グループ 3：ウパダシチニブ 30 mg QD（投与 1 日目～投与 16 週時）→ ウパダシチニブ 30 mg QD 又はプラセボ（投与 16 週時以降） グループ 4：プラセボ（投与 1 日目～投与 16 週時）→ ウパダシチニブ 30 mg QD 又はプラセボ（投与 16 週時以降） 第 1 ピリオドでは，投与 4～12 週時の間の連続する 2 回の来院時に EASI スコアがベースラインから 25%以上悪化した被験者は，治験薬の投与中止が必須であった。 第 2 ピリオドでは，プラセボ群，ウパダシチニブ 7.5 mg 群，ウパダシチニブ 15 mg 群又はウパダシチニブ 30 mg 群に再度割り付けられた被験者に対し，投与 20 週時（第 2 ピリオドでの再割付けの 4 週間後）以降の来院時に，EASI スコアのベースラインからの 50%以上の低下（以下「EASI 50」）未満となった場合は，レスキュー治療として盲検下でウパダシチニブ 30 mg QD 投与を開始し，試験終了時まで継続した。 第 2 ピリオドの期間中，投与 20 週時以降のいずれかの来院時に再度 EASI 50 未満となった被験者は，投与 24 週時以降，クラス 3～4（中力価）の副腎皮質ステロイド外用薬の併用が可能であった。副腎皮質ステロイド外用薬のレスキュー治療を受けた被験者は，4 週間後に追加の来院が必要であった。副腎皮質ステロイド外用薬のレスキュー治療を受けて 4 週間以降に EASI 50 未満となった被験者は，治験薬の投与中止が必須であった。 治験薬の投与中止後も，治験を中止（同意撤回）しない場合は規定来院を継続して追跡調査を行い，有効性及び安全性評価の欠測データを最小限にすることとした。
被験薬，用量 / 含量 / 濃度，投与法，ロット番号： ウパダシチニブ 7.5 mg 徐放錠（経口），バルクロット番号：[redacted], [redacted], [redacted], [redacted] ウパダシチニブ 15 mg 徐放錠（経口），バルクロット番号：[redacted], [redacted], [redacted], [redacted], [redacted], [redacted] ウパダシチニブ 30 mg 徐放錠（経口），バルクロット番号：[redacted], [redacted], [redacted], [redacted], [redacted] 治療期間：第 1 ピリオド：16 週間，第 2 ピリオド：72 週間
対照薬，用量 / 含量 / 濃度，投与法，ロット番号： 第 1 ピリオド及び第 2 ピリオドで対照薬としてプラセボを用いた。 ウパダシチニブに対応するプラセボの錠剤（経口），バルクロット番号：[redacted], [redacted]

評価基準：
有効性：
主要評価項目は，投与 16 週時の EASI スコアのベースライン（投与 1 日目）からの平均変化率（%）であった。
副次評価項目は以下のとおりであった。

- 投与 16 週時に EASI 75 を達成した被験者の割合（EASI 75 はベースライン［投与 1 日目］と比較して EASI スコアの 75%以上の低下と定義）
- 投与 16 週時に IGA が「0」又は「1」に達した被験者の割合
- かゆみの数値評価尺度（以下「NRS」）のベースライン（投与 1 日目）から投与 2，8 及び 16 週時までの変化率
- EASI スコアのベースライン（投与 1 日目）から投与 8 週時までの変化率
- アトピー性皮膚炎の重症度分類（以下「SCORAD」）スコアのベースライン（投与 1 日目）から投与 8 及び 16 週時までの変化率
- 投与 8 及び 16 週時に EASI スコアのベースライン（投与 1 日目）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
- 投与 8 及び 16 週時に SCORAD スコアのベースライン（投与 1 日目）からの 50%/75%/90%以上の低下（以下「SCORAD 50/75/90」）を達成した被験者の割合
- 投与 8 及び 16 週時に皮膚科関連 QOL 評価指標（以下「DLQI」）=「0」又は「1」であった被験者の割合
- ベースライン（投与 1 日目）から投与 8 及び 16 週時までの DLQI の変化
- すべての第 2 ピリオドの来院の投与 16 週時（再割付け）からの EASI スコアの変化と変化率
- 投与 16 週時に EASI 75 レスポンダーとして再割付けされた被験者のベースライン（投与 1 日目）からの EASI 50 反応率の喪失時間
- 投与 16 週時に EASI 75 ノンレスポンダーとして再割付けされた被験者のすべての第 2 ピリオドの来院での EASI 75 の概要

探索的評価項目は以下のとおりであった。

- 第 1 ピリオドにおける EASI 50/75/90 及び IGA「0」又は「1」までの期間
- すべての来院時点で EASI スコアのベースライン（投与 1 日目）からの 50%/75%/90%/100%以上の低下を達成した被験者の割合
- すべての来院時点で SCORAD 50/75/90 反応を達成した被験者の割合
- ベースライン（投与 1 日目）から投与 16 週時までの患者評価による湿疹重症度の変化
- 医学的アウトカム研究睡眠スケールのベースライン（投与 1 日目）から投与 16 週時までの変化量
- 喘息症状に関する質問票のベースライン（投与 1 日目）から投与 16 週時までの変化量
- 日中の鼻症状質問票のベースライン（投与 1 日目）から投与 16 週時までの変化量
- アクチグラフィにより測定した，一晩あたりの総睡眠時間（分），睡眠効率（%），途中覚醒時間，1 時間あたりの引っ掻き行動数及び休息（睡眠）中の平均引っ掻き行動数のベースライン（投与 1 日目）からの変化量

薬物動態：
投与 2 週時から来院ごと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。

安全性：
試験期間を通して，有害事象，身体検査，臨床検査，心電図及びバイタルサインのデータを評価した。

統計手法：

有効性：

第 1 ピリオドでは，各ウパダシチニブ投与群とプラセボ群の群間比較を行った。第 2 ピリオドでは，すべての投与群について記述統計を要約した。2 値変数は頻度とパーセンテージ（%）を，連続変数は平均値及び標準誤差を示した。

薬物動態：

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。

安全性：

安全性は，実際に受けた投与に基づいて解析した。有害事象，身体検査，臨床検査，心電図及びバイタルサインにより安全性を評価した。曝露期間で調整した有害事象の発現率（100 人年あたりの発現件数）の集計表及び有害事象が発現した被験者の一覧を，ICH 国際医薬用語集（以下「MedDRA」）の器官別大分類及び基本語別，重症度別並びに治験責任（担当）医師が評価した治験薬との因果関係別に示した。

バイタルサイン及び臨床検査値のベースラインからの変化量を評価した。欠測値の補完は行わなかった。

要約 / 結論：

有効性の結果：

本盲検プラセボ対照試験では，ウパダシチニブ 7.5 mg QD，15 mg QD 及び 30 mg QD の 16 週間投与は，中等症から重症の成人アトピー性皮膚炎患者に対して有効であった。本治験の第 1 ピリオドでは，ウパダシチニブのいずれの投与群でも，主要評価項目（EASI スコアの改善率）及び重要な副次評価項目（EASI 75 を達成した被験者及び IGA が「0」又は「1」に達した被験者の割合を含む）で有効性が認められた。すべての重要な評価項目で，明らかな用量反応関係が示された。投与 16 週時に EASI 75 を達成した被験者及び IGA が「0」又は「1」に達した被験者の割合について，ウパダシチニブ各用量群とプラセボ群との差はいずれも統計学的に有意であった（7.5 mg 群：$P < 0.05$，15 mg 群及び 30 mg 群：$P < 0.001$）。ウパダシチニブ 15 mg 群及び 30 mg 群のいずれでも，かゆみでは投与 1 週時，EASI 75 では投与 2 週時といずれも早期に統計学的に有意な治療効果が認められ，投与 8 週時までにプラトーに達した。ウパダシチニブ投与による効果の早期発現は，他の複数の有効性の評価項目でも認められ，投与 2 週時と早期に統計学的に有意な差が得られ，改善効果は投与 16 週時まで持続した。

第 2 ピリオドでは，ウパダシチニブ 30 mg 群及び 15 mg 群で，投与 32 週時に EASI 75 及びかゆみの NRS の 4 以上減少を達成した被験者の割合の点推定値は，投与を中止した被験者と比較して投与を継続した被験者で高く，統計学的に有意な差が認められた。投与を中止した被験者群では，投与を継続した被験者群と比較して EASI 50 の喪失が早期に認められ，EASI 50 を喪失した被験者の割合も，投与を継続した被験者群と比較して高かった。プラセボからウパダシチニブ 30 mg へ切り替えた被験者では，第 1 ピリオドのウパダシチニブ 30 mg 群で認められた有効性と同程度の結果が確認された。

ベースラインから投与 88 週時までウパダシチニブ 7.5 mg，15 mg 又は 30 mg の投与を受けていた被験者では，有効性の反応は維持又は更に改善された。ウパダシチニブ 30 mg は第 1 ピリオド及び第 2 ピリオドを通して，すべての有効性の評価項目で，いずれの時点でも最大の有効性を示した。

薬物動態の結果：

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，ウパダシチニブ 7.5 mg 群で 3.07～9.69 ng/mL，ウパダシチニブ 15 mg 群で 8.38～26.3 ng/mL，及びウパダシチニブ 30 mg 群（治験開始時から 30 mg QD の投与を受けていた被験者及び投与 16 週時以降にプラセボから切り替えた被験者）で 22.1～49.0 ng/mL であった。

安全性の結果：

88 週間の盲検投与期間中，有害事象（重篤な有害事象，特に注目すべき有害事象，臨床検査値及びバイタルサインを含む）の発現割合によって評価した，ウパダシチニブ 7.5 mg，15 mg 及び 30 mg の忍容性はおおむね良好

であった。

第 1 ピリオドでは死亡は報告されなかった。第 2 ピリオドへ移行し，ウパダシチニブ 30 mg の投与を受けた被験者 2 名で死亡が報告された。1 名（プラセボ / ウパダシチニブ 30 mg）が，ウパダシチニブ投与開始の 194 日後，通常の心臓アブレーション処置の合併症に続発して，食道瘻，敗血症及び心膜炎を発現した。治験薬は投与中止となり，被験者は 4.5 ヵ月後に死亡し，食道瘻，敗血症及び心膜炎が死因として報告された。残り 1 名の被験者（ウパダシチニブ 30 mg / プラセボ / レスキュー治療のウパダシチニブ 30 mg）は，第 2 ピリオドに心肺停止を発現し，ウパダシチニブの最終投与から 2 日後に自宅で死亡した。

投与 16 週時まで（第 1 ピリオド），有害事象を発現した被験者の割合は，いずれのウパダシチニブ群でも同程度であり，プラセボ群よりわずかに高かった。最も多く認められた有害事象は，上気道感染，ざ瘡及びアトピー性皮膚炎であり，いずれの発現割合もいずれかの投与群で 5%以上であった。第 1 ピリオド及び第 2 ピリオドを通して最も多く認められた有害事象は，ざ瘡を除き，投与 16 週時まで（第 1 ピリオド）と同様であった。治験薬の投与中止に至った有害事象及び重篤な有害事象の発現割合に用量依存性は認められず，ウパダシチニブ 30 mg 群で重篤な有害事象は報告されなかった。

第 1 ピリオド及び第 2 ピリオドを通して，治験薬の投与中止に至った有害事象の発現率は，ウパダシチニブ 15 mg 群（9.7 件 / 100 人年）及びウパダシチニブ 30 mg 群（10.0 件 / 100 人年）と比較して，ウパダシチニブ 7.5 mg 群（32.9 件 / 100 人年）で高かった。同様に，第 1 ピリオド及び第 2 ピリオドを通して，重篤な有害事象の発現率は，ウパダシチニブ 15 mg 群（4.8 件 / 100 人年）及びウパダシチニブ 30 mg 群（6.9 件 / 100 人年）と比較して，ウパダシチニブ 7.5 mg 群（19.7 件 / 100 人年）で高かった。

投与 16 週時まで（第 1 ピリオド），事前に規定した特に注目すべき有害事象は，いずれの投与群でもほとんど認められなかった。ウパダシチニブ群の特に注目すべき有害事象の発現割合は，おおむねプラセボ群と同程度であったが，重篤な感染症，肝障害，好中球減少症及びクレアチンホスホキナーゼ増加は，ウパダシチニブ群でより発現割合が高かった。投与 16 週時まで，いずれの投与群の被験者でも，治験薬投与後に日和見感染，悪性腫瘍，消化管穿孔，帯状疱疹，腎機能障害，活動性 / 潜伏結核，判定された心血管事象及び肺塞栓症は認められなかった。投与 16 週時まで（第 1 ピリオド）に，重篤な感染症が 3 件（ウパダシチニブ 7.5 mg 群で 2 名及び 15 mg 群で 1 名）認められた。肝障害が，ウパダシチニブ 15 mg 群の 2 名及びプラセボ群の 1 名で報告された。貧血，好中球減少症及びリンパ球減少症は，ウパダシチニブ群のみで報告され，プラセボ群では報告されず，これらの有害事象は，いずれの投与群でも 3 名以上では報告されなかった。クレアチンホスホキナーゼ増加の発現割合は，プラセボ群と比較してウパダシチニブ 15 mg 群及び 30 mg 群で高く，ウパダシチニブ 7.5 mg 群では報告されなかった。いずれも無症候性であり，横紋筋融解症は報告されなかった。ざ瘡の発現に，明らかな用量依存性は認められず，いずれの投与群でも報告された。ざ瘡の重症度は，いずれも軽度又は中等度であった。

第 1 ピリオド及び第 2 ピリオドを通して，重篤な感染症の発現率は，ウパダシチニブ 15 mg 群（4.8 件 / 100 人年）及びウパダシチニブ 30 mg 群（0.8 件 / 100 人年）と比較して，ウパダシチニブ 7.5 mg 群（13.2 件 / 100 人年）で高かった。第 1 ピリオド及び第 2 ピリオドを通して，いずれの投与群でも，治験薬投与後に日和見感染，腎機能障害，活動性 / 潜伏結核及び不整脈は認められなかった。判定された主要心血管事象は認められなかった。帯状疱疹はウパダシチニブ 30 mg 群（7.7 件 / 100 人年）のみで報告され，いずれの帯状疱疹も，単一の皮節のみに認められた。ウパダシチニブ 30 mg 群の 2 名で悪性腫瘍が報告された（菌状息肉症［医師記載名：皮膚 T 細胞性リンパ腫］が 1 名で報告され，皮膚有棘細胞癌が 1 名で 3 件報告された）。試験期間中に血栓塞栓症関連事象を発現した被験者は，複数の危険因子を有していた 1 名（肺塞栓症；ウパダシチニブ 30 mg / プラセボ / レスキュー治療のウパダシチニブ 30 mg）のみであった。貧血は，ウパダシチニブ 30 mg の投与を受けた被験者のみで報告され，ウパダシチニブ 7.5 mg 群及び 15 mg 群では報告されなかった。全体として，肝障害，好中球減少症，リンパ球減少症及びクレアチンホスホキナーゼ増加の 100 人年あたりの発現率は，ウパダシチニブ 30 mg 群及びウパダシチニブ 7.5 mg 群と比較して，ウパダシチニブ 15 mg 群で最も高かった。肝障害，クレアチンホスホキナーゼ増加，貧血，好中球減少症及びリンパ球減少症によって治験薬の投与中止に至った被験者はいなかった。88 週間を通して，臨床検査値に臨床的に重要な変化は認められなかった。

結論：

本試験（M16-048 試験）の投与 16 週時までに，ウパダシチニブは中等症から重症の成人アトピー性皮膚炎患者に対し，主な臨床反応及び患者報告健康アウトカムにおいて，用量依存性及び曝露量依存性の有効性を示し，プラセボと比較してウパダシチニブ 7.5 mg，15 mg 及び 30 mg QD の有効性が示された。本試験では，アトピー性

皮膚炎に対するウパダシチニブの有効性（EASI 反応，IGA「0」又は「1」及びかゆみ）の用量依存的な増加が認められた。ウパダシチニブの継続的な投与を受けた被験者では，投与 88 週時まで有効性が維持又は更に改善された。ウパダシチニブの投与中止によって，多数の被験者で疾患抑制効果の減少が認められた。しかし，ウパダシチニブ 30 mg によるレスキュー治療によって有効性が再度認められた。データが入手可能な他の適応症（関節リウマチ，強直性脊椎炎，クローン病及び潰瘍性大腸炎）と比較して，ウパダシチニブの新たな重要な安全性の懸念は認められなかった。本試験の投与 88 週時までの有効性及び安全性の結果に基づき，検討した全用量でのウパダシチニブのベネフィット・リスクのプロファイルは良好と考えられた。

表 1. 第 1 ピリオドで有害事象を発現した被験者数及び発現割合：MedDRA のプライマリー器官別大分類及び基本語別（第 1 ピリオドの安全性解析対象集団）

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	PLACEBO (N=40) n (%)	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=42) n (%)	UPA TOTAL (N=126) n (%)
ANY ADVERSE EVENT	25 (62.5)	31 (73.8)	32 (76.2)	33 (78.6)	96 (76.2)
血液およびリンパ系障害					
貧血	0	0	0	1 (2.4)	1 (0.8)
内出血発生の増加傾向	0	0	0	1 (2.4)	1 (0.8)
リンパ節炎	0	0	0	1 (2.4)	1 (0.8)
リンパ節症	0	1 (2.4)	0	0	1 (0.8)
リンパ球減少症	0	0	1 (2.4)	0	1 (0.8)
好中球減少症	0	1 (2.4)	2 (4.8)	2 (4.8)	5 (4.0)
SUBJECTS WITH ONE OR MORE EVENTS	0	2 (4.8)	2 (4.8)	5 (11.9)	9 (7.1)
心臓障害					
心房細動	1 (2.5)	0	0	0	0
動悸	0	0	1 (2.4)	0	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.5)	0	1 (2.4)	0	1 (0.8)
内分泌障害					

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	PLACEBO (N=40) n (%)	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=42) n (%)	UPA TOTAL (N=126) n (%)
甲状腺腫	0	1 (2.4)	0	0	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (2.4)	0	0	1 (0.8)
眼障害					
白内障	0	0	0	1 (2.4)	1 (0.8)
霰粒腫	0	1 (2.4)	0	0	1 (0.8)
ドライアイ	0	0	1 (2.4)	0	1 (0.8)
眼刺激	0	0	0	1 (2.4)	1 (0.8)
流涙増加	0	0	1 (2.4)	1 (2.4)	2 (1.6)
点状角膜炎	0	0	1 (2.4)	0	1 (0.8)
潰瘍性角膜炎	0	1 (2.4)	0	0	1 (0.8)
霧視	0	0	0	1 (2.4)	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	0	2 (4.8)	3 (7.1)	4 (9.5)	9 (7.1)
胃腸障害					
腹痛	1 (2.5)	0	2 (4.8)	1 (2.4)	3 (2.4)
上腹部痛	0	0	1 (2.4)	0	1 (0.8)
下痢	2 (5.0)	2 (4.8)	2 (4.8)	0	4 (3.2)
消化不良	0	0	0	1 (2.4)	1 (0.8)
胃炎	0	0	1 (2.4)	0	1 (0.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	PLACEBO (N=40) n (%)	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=42) n (%)	UPA TOTAL (N=126) n (%)
消化器痛	0	1 (2.4)	0	0	1 (0.8)
悪心	1 (2.5)	3 (7.1)	1 (2.4)	3 (7.1)	7 (5.6)
SUBJECTS WITH ONE OR MORE EVENTS	4 (10.0)	3 (7.1)	5 (11.9)	5 (11.9)	13 (10.3)
一般・全身障害および投与部位の状態					
嚢胞	0	0	0	1 (2.4)	1 (0.8)
顔面浮腫	0	0	0	1 (2.4)	1 (0.8)
疲労	0	1 (2.4)	2 (4.8)	2 (4.8)	5 (4.0)
インフルエンザ様疾患	1 (2.5)	0	1 (2.4)	0	1 (0.8)
非心臓性胸痛	0	0	0	1 (2.4)	1 (0.8)
浮腫	0	1 (2.4)	0	1 (2.4)	2 (1.6)
末梢性浮腫	1 (2.5)	0	0	1 (2.4)	1 (0.8)
疼痛	0	0	0	1 (2.4)	1 (0.8)
末梢腫脹	0	1 (2.4)	0	0	1 (0.8)
発熱	1 (2.5)	1 (2.4)	0	0	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	3 (7.5)	3 (7.1)	2 (4.8)	6 (14.3)	11 (8.7)
肝胆道系障害					
脂肪肝	0	0	1 (2.4)	0	1 (0.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	PLACEBO (N=40) n (%)	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=42) n (%)	UPA TOTAL (N=126) n (%)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	1 (2.4)	0	1 (0.8)
感染症および寄生虫症					
膿瘍	0	1 (2.4)	0	0	1 (0.8)
虫垂炎	0	0	1 (2.4)	0	1 (0.8)
ボトリオミセス症	0	0	0	1 (2.4)	1 (0.8)
蜂巣炎	1 (2.5)	0	0	0	0
結膜炎	0	2 (4.8)	0	0	2 (1.6)
眼感染	0	1 (2.4)	0	0	1 (0.8)
毛包炎	0	2 (4.8)	2 (4.8)	0	4 (3.2)
胃腸炎	1 (2.5)	1 (2.4)	1 (2.4)	1 (2.4)	3 (2.4)
単純ヘルペス	0	0	2 (4.8)	1 (2.4)	3 (2.4)
麦粒腫	1 (2.5)	0	0	0	0
膿痂疹	0	1 (2.4)	0	2 (4.8)	3 (2.4)
インフルエンザ	0	3 (7.1)	0	0	3 (2.4)
下気道感染	0	0	1 (2.4)	0	1 (0.8)
リンパ管炎	0	0	1 (2.4)	0	1 (0.8)
上咽頭炎	1 (2.5)	2 (4.8)	4 (9.5)	3 (7.1)	9 (7.1)
口腔ヘルペス	0	0	1 (2.4)	0	1 (0.8)
外耳炎	0	0	1 (2.4)	0	1 (0.8)
爪囲炎	0	0	1 (2.4)	0	1 (0.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	PLACEBO (N=40) n (%)	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=42) n (%)	UPA TOTAL (N=126) n (%)
歯冠周囲炎	0	1 (2.4)	0	0	1 (0.8)
レンサ球菌性咽頭炎	0	1 (2.4)	0	0	1 (0.8)
術後創感染	0	0	1 (2.4)	0	1 (0.8)
腎盂腎炎	0	0	0	1 (2.4)	1 (0.8)
膿疱性皮疹	0	1 (2.4)	2 (4.8)	0	3 (2.4)
鼻炎	1 (2.5)	0	1 (2.4)	1 (2.4)	2 (1.6)
副鼻腔炎	0	0	1 (2.4)	1 (2.4)	2 (1.6)
皮膚感染	1 (2.5)	2 (4.8)	0	0	2 (1.6)
ブドウ球菌感染	0	1 (2.4)	0	0	1 (0.8)
歯感染	0	0	1 (2.4)	1 (2.4)	2 (1.6)
上気道感染	4 (10.0)	7 (16.7)	5 (11.9)	5 (11.9)	17 (13.5)
尿路感染	0	2 (4.8)	2 (4.8)	1 (2.4)	5 (4.0)
ウイルス性上気道感染	0	0	0	1 (2.4)	1 (0.8)
外陰腟真菌感染	0	0	0	1 (2.4)	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	9 (22.5)	22 (52.4)	18 (42.9)	17 (40.5)	57 (45.2)
傷害、中毒および処置合併症					
節足動物咬傷	0	1 (2.4)	1 (2.4)	0	2 (1.6)
挫傷	0	0	0	1 (2.4)	1 (0.8)
顔面損傷	0	0	0	1 (2.4)	1 (0.8)
転倒	1 (2.5)	0	0	0	0

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	PLACEBO (N=40) n (%)	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=42) n (%)	UPA TOTAL (N=126) n (%)
靭帯捻挫	2 (5.0)	0	0	0	0
四肢損傷	0	0	0	1 (2.4)	1 (0.8)
外傷後頚部症候群	0	1 (2.4)	0	0	1 (0.8)
交通事故	0	1 (2.4)	0	1 (2.4)	2 (1.6)
皮膚裂傷	0	0	1 (2.4)	2 (4.8)	3 (2.4)
サンバーン	0	0	0	1 (2.4)	1 (0.8)
歯牙破折	0	1 (2.4)	0	0	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	3 (7.5)	3 (7.1)	2 (4.8)	5 (11.9)	10 (7.9)
臨床検査					
アラニンアミノトランスフェラーゼ増加	1 (2.5)	0	0	0	0
アスパラギン酸アミノトランスフェラーゼ増加	1 (2.5)	0	0	0	0
血中ビリルビン増加	0	0	1 (2.4)	0	1 (0.8)
血中コレステロール増加	0	0	0	1 (2.4)	1 (0.8)
血中クレアチン増加	1 (2.5)	0	0	0	0
血中クレアチンホスホキナーゼ増加	2 (5.0)	0	3 (7.1)	4 (9.5)	7 (5.6)
血中テストステロン減少	0	0	1 (2.4)	0	1 (0.8)
血中トリグリセリド増加	0	0	1 (2.4)	1 (2.4)	2 (1.6)
子宮頚部スミア異常	0	0	1 (2.4)	0	1 (0.8)
体重増加	0	1 (2.4)	0	0	1 (0.8)
白血球数減少	0	0	1 (2.4)	0	1 (0.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	PLACEBO (N=40) n (%)	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=42) n (%)	UPA TOTAL (N=126) n (%)
SUBJECTS WITH ONE OR MORE EVENTS	4 (10.0)	1 (2.4)	7 (16.7)	5 (11.9)	13 (10.3)
代謝および栄養障害					
食欲減退	0	1 (2.4)	0	0	1 (0.8)
脱水	0	0	0	1 (2.4)	1 (0.8)
高コレステロール血症	0	0	1 (2.4)	0	1 (0.8)
高トリグリセリド血症	0	0	0	2 (4.8)	2 (1.6)
低ナトリウム血症	1 (2.5)	0	0	0	0
ビタミン B12 欠乏	0	1 (2.4)	0	0	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.5)	2 (4.8)	1 (2.4)	3 (7.1)	6 (4.8)
筋骨格系および結合組織障害					
関節痛	1 (2.5)	1 (2.4)	0	1 (2.4)	2 (1.6)
背部痛	1 (2.5)	1 (2.4)	0	0	1 (0.8)
筋痙縮	0	0	1 (2.4)	0	1 (0.8)
筋骨格系胸痛	0	1 (2.4)	0	1 (2.4)	2 (1.6)
筋肉痛	1 (2.5)	0	0	1 (2.4)	1 (0.8)
頚部痛	0	0	0	1 (2.4)	1 (0.8)
四肢痛	1 (2.5)	0	0	0	0
腱障害	0	0	0	1 (2.4)	1 (0.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	PLACEBO (N=40) n (%)	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=42) n (%)	UPA TOTAL (N=126) n (%)
SUBJECTS WITH ONE OR MORE EVENTS	4 (10.0)	2 (4.8)	1 (2.4)	4 (9.5)	7 (5.6)
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）					
脂漏性角化症	0	0	0	1 (2.4)	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	1 (2.4)	1 (0.8)
神経系障害					
注意力障害	0	0	1 (2.4)	0	1 (0.8)
浮動性めまい	0	0	1 (2.4)	2 (4.8)	3 (2.4)
頭痛	1 (2.5)	3 (7.1)	3 (7.1)	4 (9.5)	10 (7.9)
感覚鈍麻	0	0	0	1 (2.4)	1 (0.8)
片頭痛	0	1 (2.4)	0	0	1 (0.8)
錯感覚	0	0	0	1 (2.4)	1 (0.8)
痙攣発作	0	0	1 (2.4)	0	1 (0.8)
傾眠	0	0	0	1 (2.4)	1 (0.8)
失神	0	0	0	1 (2.4)	1 (0.8)
緊張性頭痛	0	1 (2.4)	0	0	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.5)	5 (11.9)	5 (11.9)	7 (16.7)	17 (13.5)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	PLACEBO (N=40) n (%)	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=42) n (%)	UPA TOTAL (N=126) n (%)
精神障害					
錯乱状態	0	0	1 (2.4)	0	1 (0.8)
うつ病	0	0	1 (2.4)	0	1 (0.8)
不眠症	1 (2.5)	0	0	0	0
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.5)	0	2 (4.8)	0	2 (1.6)
腎および尿路障害					
血尿	2 (5.0)	0	0	0	0
腎症	0	0	0	1 (2.4)	1 (0.8)
蛋白尿	2 (5.0)	0	0	0	0
SUBJECTS WITH ONE OR MORE EVENTS	3 (7.5)	0	0	1 (2.4)	1 (0.8)
生殖系および乳房障害					
無月経	0	0	0	1 (2.4)	1 (0.8)
生殖器病変	1 (2.5)	0	0	0	0
月経前頭痛	0	0	0	1 (2.4)	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.5)	0	0	2 (4.8)	2 (1.6)
呼吸器、胸郭および縦隔障害					

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	PLACEBO (N=40) n (%)	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=42) n (%)	UPA TOTAL (N=126) n (%)
咳嗽	0	0	1 (2.4)	0	1 (0.8)
呼吸困難	0	0	1 (2.4)	0	1 (0.8)
鼻出血	0	0	1 (2.4)	0	1 (0.8)
口腔咽頭痛	0	3 (7.1)	0	0	3 (2.4)
湿性咳嗽	0	1 (2.4)	0	0	1 (0.8)
肺腫瘤	1 (2.5)	0	0	0	0
アレルギー性鼻炎	1 (2.5)	0	0	0	0
副鼻腔うっ血	0	0	0	1 (2.4)	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	2 (5.0)	3 (7.1)	2 (4.8)	1 (2.4)	6 (4.8)
皮膚および皮下組織障害					
ざ瘡	1 (2.5)	4 (9.5)	2 (4.8)	6 (14.3)	12 (9.5)
脱毛症	1 (2.5)	0	0	0	0
ざ瘡様皮膚炎	0	0	1 (2.4)	0	1 (0.8)
アトピー性皮膚炎	2 (5.0)	6 (14.3)	2 (4.8)	4 (9.5)	12 (9.5)
接触皮膚炎	2 (5.0)	0	1 (2.4)	1 (2.4)	2 (1.6)
皮膚乾燥	1 (2.5)	0	0	0	0
ケロイド瘢痕	0	0	1 (2.4)	0	1 (0.8)
寝汗	0	0	2 (4.8)	0	2 (1.6)
斑状丘疹状皮疹	0	0	1 (2.4)	0	1 (0.8)
皮膚局面	0	1 (2.4)	0	0	1 (0.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	PLACEBO (N=40) n (%)	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=42) n (%)	UPA TOTAL (N=126) n (%)
SUBJECTS WITH ONE OR MORE EVENTS	6 (15.0)	10 (23.8)	10 (23.8)	10 (23.8)	30 (23.8)

NOTE: TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS ANY ADVERSE EVENT WITH AN ONSET DATE ON OR AFTER THE FIRST DOSE OF STUDY DRUG IN PERIOD 1 AND PRIOR TO THE FIRST DOSE OF STUDY DRUG IN PERIOD 2 OR UP TO 30 DAYS AFTER THE LAST DOSE OF STUDY DRUG IF SUBJECT DISCONTINUED STUDY DRUG PREMATURELY FROM PERIOD 1 OF THE STUDY.
THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.

Program Source Code: [redacted]
相互参照：M16-048 試験 CSR Table 14.3__1.2.1.1

表 2. 第 2 ピリオドでウパダシチニブ 30 mg のレスキュー治療を行う前に有害事象を発現した被験者数及び発現割合：MedDRA のプライマリー器官別大分類及び基本語別（第 2 ピリオドの安全性解析対象集団）

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	PLACEBO/ PLACEBO (N=10) n (%)	PLACEBO/ UPA 30 MG QD (N=10) n (%)	UPA 7.5 MG QD/ PLACEBO (N=15) n (%)	UPA 7.5 MG QD/ UPA 7.5 MG QD (N=16) n (%)	UPA 15 MG QD/ PLACEBO (N=19) n (%)	UPA 15 MG QD/ UPA 15 MG QD (N=18) n (%)	UPA 30 MG QD/ PLACEBO (N=19) n (%)	UPA 30 MG QD/ UPA 30 MG QD (N=19) n (%)	OVERALL TOTAL (N=126) n (%)
ANY ADVERSE EVENT	2 (20.0)	8 (80.0)	1 (6.7)	4 (25.0)	6 (31.6)	8 (44.4)	8 (42.1)	11 (57.9)	48 (38.1)
血液およびリンパ系障害									
好中球減少症	0	0	0	0	0	0	0	1 (5.3)	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	0	0	0	0	1 (5.3)	1 (0.8)
心臓障害									
心膜炎	0	1 (10.0)	0	0	0	0	0	0	1 (0.8)
洞結節機能不全	0	1 (10.0)	0	0	0	0	0	0	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (10.0)	0	0	0	0	0	0	1 (0.8)
耳および迷路障害									
回転性めまい	0	0	0	0	1 (5.3)	0	0	0	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	0	1 (5.3)	0	0	0	1 (0.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	PLACEBO/ PLACEBO (N=10) n (%)	UPA 30 MG QD/ UPA 30 MG QD (N=10) n (%)	UPA 7.5 MG QD/ PLACEBO (N=15) n (%)	UPA 7.5 MG QD/ UPA 7.5 MG QD (N=16) n (%)	UPA 15 MG QD/ PLACEBO (N=19) n (%)	UPA 15 MG QD/ UPA 15 MG QD (N=18) n (%)	UPA 30 MG QD/ PLACEBO (N=19) n (%)	UPA 30 MG QD/ UPA 30 MG QD (N=19) n (%)	OVERALL TOTAL (N=126) n (%)
胃腸障害									
下痢	0	0	0	0	0	1 (5.6)	0	0	1 (0.8)
変色便	0	0	0	0	1 (5.3)	0	0	0	1 (0.8)
胃炎	0	0	0	0	0	0	0	1 (5.3)	1 (0.8)
悪心	0	0	0	0	0	0	1 (5.3)	0	1 (0.8)
食道瘻	0	1 (10.0)	0	0	0	0	0	0	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (10.0)	0	0	1 (5.3)	1 (5.6)	1 (5.3)	1 (5.3)	5 (4.0)
一般・全身障害および投与部位の状態									
疲労	0	0	0	0	0	1 (5.6)	0	0	1 (0.8)
インフルエンザ様疾患	0	0	0	0	0	1 (5.6)	0	0	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	0	0	1 (5.6)	0	0	1 (0.8)
免疫系障害									
過敏症	0	0	0	0	1 (5.3)	0	0	0	1 (0.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	PLACEBO/ PLACEBO (N=10) n (%)	UPA 30 MG QD/ PLACEBO (N=10) n (%)	UPA 7.5 MG QD/ PLACEBO (N=15) n (%)	UPA 7.5 MG QD (N=16) n (%)	UPA 15 MG QD/ PLACEBO (N=19) n (%)	UPA 15 MG QD (N=18) n (%)	UPA 30 MG QD/ PLACEBO (N=19) n (%)	UPA 30 MG QD (N=19) n (%)	OVERALL TOTAL (N=126) n (%)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	0	1 (5.3)	0	0	0	1 (0.8)
感染症および寄生虫症									
細菌性膣症	0	0	0	0	0	0	1 (5.3)	0	1 (0.8)
気管支炎	0	0	0	0	0	0	0	1 (5.3)	1 (0.8)
膀胱炎	0	0	0	0	0	0	1 (5.3)	0	1 (0.8)
ヘルペス性状湿疹	0	0	0	0	0	0	0	1 (5.3)	1 (0.8)
胃腸炎	0	1 (10.0)	0	0	0	0	0	0	1 (0.8)
帯状疱疹	0	0	0	0	0	0	0	1 (5.3)	1 (0.8)
麦粒腫	0	0	0	0	0	0	1 (5.3)	0	1 (0.8)
膿痂疹	0	1 (10.0)	0	0	0	0	1 (5.3)	1 (5.3)	3 (2.4)
下気道感染	0	0	0	0	0	0	0	1 (5.3)	1 (0.8)
上咽頭炎	0	0	0	1 (6.3)	0	1 (5.6)	0	1 (5.3)	3 (2.4)
レンサ球菌性咽頭炎	0	0	0	0	0	0	0	1 (5.3)	1 (0.8)
敗血症	0	1 (10.0)	0	0	0	0	0	0	1 (0.8)
副鼻腔炎	0	0	0	1 (6.3)	0	0	0	0	1 (0.8)
皮膚感染	0	0	1 (6.7)	0	0	0	0	0	1 (0.8)
上気道感染	0	3 (30.0)	0	0	1 (5.3)	1 (5.6)	1 (5.3)	3 (15.8)	9 (7.1)
尿路感染	0	0	0	0	0	0	0	2 (10.5)	2 (1.6)
外陰膣真菌感染	0	0	0	0	1 (5.3)	0	0	0	1 (0.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	PLACEBO/ PLACEBO (N=10) n (%)	PLACEBO/ UPA 30 MG QD (N=10) n (%)	UPA 7.5 MG QD/ PLACEBO (N=15) n (%)	UPA 7.5 MG QD/ UPA 7.5 MG QD (N=16) n (%)	UPA 15 MG QD/ PLACEBO (N=19) n (%)	UPA 15 MG QD/ UPA 15 MG QD (N=18) n (%)	UPA 30 MG QD/ PLACEBO (N=19) n (%)	UPA 30 MG QD/ UPA 30 MG QD (N=19) n (%)	OVERALL TOTAL (N=126) n (%)
SUBJECTS WITH ONE OR MORE EVENTS	0	5 (50.0)	1 (6.7)	2 (12.5)	2 (10.5)	2 (11.1)	4 (21.1)	8 (42.1)	24 (19.0)
傷害、中毒および処置合併症									
転倒	0	1 (10.0)	0	0	0	0	0	0	1 (0.8)
四肢損傷	0	0	0	0	0	0	0	1 (5.3)	1 (0.8)
処置による疼痛	0	0	0	0	0	1 (5.6)	0	0	1 (0.8)
歯牙破折	0	0	0	0	0	0	1 (5.3)	0	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (10.0)	0	0	0	1 (5.6)	1 (5.3)	1 (5.3)	4 (3.2)
臨床検査									
アラニンアミノトランスフェラーゼ増加	1 (10.0)	0	0	0	0	0	0	0	1 (0.8)
アスパラギン酸アミノトランスフェラーゼ増加	1 (10.0)	0	0	0	0	0	0	0	1 (0.8)
血中クレアチンホスホキナーゼ増加	1 (10.0)	0	0	0	0	0	0	2 (10.5)	3 (2.4)
血中尿酸増加	0	0	0	0	1 (5.3)	0	0	0	1 (0.8)
肝酵素上昇	0	0	0	0	0	0	0	1 (5.3)	1 (0.8)
赤血球数減少	0	0	0	0	1 (5.3)	0	0	0	1 (0.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	PLACEBO/ PLACEBO (N=10) n (%)	PLACEBO/ UPA 30 MG QD (N=10) n (%)	UPA 7.5 MG QD/ PLACEBO (N=15) n (%)	UPA 7.5 MG QD/ UPA 7.5 MG QD (N=16) n (%)	UPA 15 MG QD/ PLACEBO (N=19) n (%)	UPA 15 MG QD/ UPA 15 MG QD (N=18) n (%)	UPA 30 MG QD/ PLACEBO (N=19) n (%)	UPA 30 MG QD/ UPA 30 MG QD (N=19) n (%)	OVERALL TOTAL (N=126) n (%)
SUBJECTS WITH ONE OR MORE EVENTS	2 (20.0)	0	0	0	2 (10.5)	0	0	3 (15.8)	7 (5.6)
代謝および栄養障害									
糖尿病	0	0	0	0	1 (5.3)	0	0	0	1 (0.8)
痛風	0	0	0	0	0	0	1 (5.3)	0	1 (0.8)
高トリグリセリド血症	0	0	0	0	0	0	0	1 (5.3)	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	0	1 (5.3)	0	1 (5.3)	1 (5.3)	3 (2.4)
筋骨格系および結合組織障害									
背部痛	0	2 (20.0)	0	0	0	0	0	0	2 (1.6)
筋骨格痛	0	0	0	0	0	1 (5.6)	0	0	1 (0.8)
筋肉痛	1 (10.0)	0	0	0	0	0	0	0	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	1 (10.0)	2 (20.0)	0	0	0	1 (5.6)	0	0	4 (3.2)
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）									
皮膚乳頭腫	0	1 (10.0)	0	0	0	1 (5.6)	0	0	2 (1.6)
皮膚有棘細胞癌	0	1 (10.0)	0	0	0	0	0	0	1 (0.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	PLACEBO/ PLACEBO (N=10) n (%)	PLACEBO/ UPA 30 MG QD (N=10) n (%)	UPA 7.5 MG QD/ PLACEBO (N=15) n (%)	UPA 7.5 MG QD/ UPA 7.5 MG QD (N=16) n (%)	UPA 15 MG QD/ PLACEBO (N=19) n (%)	UPA 15 MG QD/ UPA 15 MG QD (N=18) n (%)	UPA 30 MG QD/ PLACEBO (N=19) n (%)	UPA 30 MG QD/ UPA 30 MG QD (N=19) n (%)	OVERALL TOTAL (N=126) n (%)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (10.0)	0	0	0	1 (5.6)	0	0	2 (1.6)
神経系障害									
頭痛	0	1 (10.0)	0	0	0	0	2 (10.5)	0	3 (2.4)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (10.0)	0	0	0	0	2 (10.5)	0	3 (2.4)
精神障害									
不安	0	0	0	0	0	1 (5.6)	0	0	1 (0.8)
うつ病	0	0	0	0	1 (5.3)	0	0	0	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	0	1 (5.3)	1 (5.6)	0	0	2 (1.6)
腎および尿路障害									
ビリルビン尿	0	1 (10.0)	0	0	0	0	0	0	1 (0.8)
腎嚢胞	0	0	0	0	0	1 (5.6)	0	0	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (10.0)	0	0	0	1 (5.6)	0	0	2 (1.6)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	PLACEBO/ PLACEBO (N=10) n (%)	UPA 30 MG QD/ UPA 30 MG QD (N=10) n (%)	UPA 7.5 MG QD/ PLACEBO (N=15) n (%)	UPA 7.5 MG QD/ UPA 7.5 MG QD (N=16) n (%)	UPA 15 MG QD/ PLACEBO (N=19) n (%)	UPA 15 MG QD/ UPA 15 MG QD (N=18) n (%)	UPA 30 MG QD/ PLACEBO (N=19) n (%)	UPA 30 MG QD/ UPA 30 MG QD (N=19) n (%)	OVERALL TOTAL (N=126) n (%)
生殖系および乳房障害									
勃起不全	0	0	0	0	0	0	0	1 (5.3)	1 (0.8)
外陰腟乾燥	0	0	0	0	0	0	1 (5.3)	0	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	0	0	0	1 (5.3)	1 (5.3)	2 (1.6)
呼吸器、胸郭および縦隔障害									
喘息	0	0	0	0	0	1 (5.6)	1 (5.3)	0	2 (1.6)
咳嗽	0	1 (10.0)	0	0	0	1 (5.6)	0	0	2 (1.6)
喀血	0	0	0	0	0	0	0	1 (5.3)	1 (0.8)
副鼻腔うっ血	0	0	0	0	0	1 (5.6)	0	0	1 (0.8)
睡眠時無呼吸症候群	0	0	0	0	0	1 (5.6)	0	0	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (10.0)	0	0	0	3 (16.7)	1 (5.3)	1 (5.3)	6 (4.8)
皮膚および皮下組織障害									
ざ瘡	0	0	0	0	0	0	0	1 (5.3)	1 (0.8)
光線角化症	0	1 (10.0)	0	0	0	0	0	0	1 (0.8)
アトピー性皮膚炎	0	0	0	1 (6.3)	1 (5.3)	2 (11.1)	0	1 (5.3)	5 (4.0)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	PLACEBO/ PLACEBO (N=10) n (%)	UPA 30 MG QD (N=10) n (%)	UPA 7.5 MG QD/ PLACEBO (N=15) n (%)	UPA 7.5 MG QD (N=16) n (%)	UPA 15 MG QD/ PLACEBO (N=19) n (%)	UPA 15 MG QD (N=18) n (%)	UPA 30 MG QD/ PLACEBO (N=19) n (%)	UPA 30 MG QD (N=19) n (%)	OVERALL TOTAL (N=126) n (%)
間擦疹	0	0	0	1 (6.3)	0	0	0	1 (5.3)	2 (1.6)
丘疹膿疱性酒さ	0	1 (10.0)	0	0	0	0	0	0	1 (0.8)
光線過敏性反応	0	0	0	0	1 (5.3)	0	0	0	1 (0.8)
ばら色粃糠疹	0	1 (10.0)	0	0	0	0	0	0	1 (0.8)
発疹	0	0	0	0	0	0	1 (5.3)	0	1 (0.8)
酒さ	0	0	0	1 (6.3)	0	0	0	0	1 (0.8)
皮膚剥脱	0	0	0	0	1 (5.3)	0	0	0	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	0	2 (20.0)	0	3 (18.8)	2 (10.5)	2 (11.1)	1 (5.3)	3 (15.8)	13 (10.3)
血管障害									
高血圧	0	0	0	1 (6.3)	0	0	0	0	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	0	1 (6.3)	0	0	0	0	1 (0.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	PLACEBO/ PLACEBO (N=10) n (%)	PLACEBO/ UPA 30 MG QD (N=10) n (%)	UPA 7.5 MG QD/ PLACEBO (N=15) n (%)	UPA 7.5 MG QD/ UPA 7.5 MG QD (N=16) n (%)	UPA 15 MG QD/ PLACEBO (N=19) n (%)	UPA 15 MG QD/ UPA 15 MG QD (N=18) n (%)	UPA 30 MG QD/ PLACEBO (N=19) n (%)	UPA 30 MG QD/ UPA 30 MG QD (N=19) n (%)	OVERALL TOTAL (N=126) n (%)

NOTE: TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS ANY ADVERSE EVENT WITH AN ONSET DATE ON OR AFTER THE FIRST DOSE OF STUDY DRUG IN PERIOD 2 AND UP TO 30 DAYS AFTER THE LAST DOSE OF STUDY DRUG, OR PRIOR TO THE FIRST DOSE OF RESCUE UPA 30 MG, WHICHEVER HAPPENED EARLIER.
THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.

Program Source Code: [redacted]
相互参照：M16-048 試験 CSR Table 14.3__1.2.1.2

表 3. 投与量ごとの第 1 ピリオド及び第 2 ピリオドで有害事象を発現した被験者数及び発現割合：MedDRA のプライマリー器官別大分類及び基本語別（第 1 ピリオド及び第 2 ピリオドの安全性解析対象集団）

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
ANY ADVERSE EVENT	33 (78.6)	33 (78.6)	88 (77.2)
血液およびリンパ系障害			
貧血	0	0	3 (2.6)
内出血発生の増加傾向	0	0	1 (0.9)
リンパ節炎	0	0	1 (0.9)
リンパ節症	1 (2.4)	0	2 (1.8)
リンパ球減少症	0	1 (2.4)	0
好中球減少症	1 (2.4)	2 (4.8)	3 (2.6)
SUBJECTS WITH ONE OR MORE EVENTS	2 (4.8)	2 (4.8)	10 (8.8)
心臓障害			
心肺停止	0	0	1 (0.9)
動悸	0	1 (2.4)	0
心膜炎	0	0	1 (0.9)
洞結節機能不全	0	0	1 (0.9)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (2.4)	2 (1.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
先天性、家族性および遺伝性障害			
角膜ジストロフィー	0	0	1 (0.9)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	1 (0.9)
耳および迷路障害			
耳痛	0	0	1 (0.9)
回転性めまい	0	1 (2.4)	0
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (2.4)	1 (0.9)
内分泌障害			
甲状腺腫	1 (2.4)	0	0
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.4)	0	0
眼障害			
白内障	0	0	1 (0.9)
霰粒腫	1 (2.4)	0	0
結膜リンパ管拡張症	0	0	1 (0.9)
アレルギー性結膜炎	0	0	1 (0.9)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
ドライアイ	0	1 (2.4)	0
眼刺激	0	0	1 (0.9)
虹彩毛様体炎	0	0	1 (0.9)
流涙増加	0	1 (2.4)	1 (0.9)
瞼板腺炎	0	0	1 (0.9)
点状角膜炎	0	1 (2.4)	0
眼瞼腫脹	0	0	1 (0.9)
潰瘍性角膜炎	1 (2.4)	0	0
ぶどう膜炎	0	0	1 (0.9)
霧視	0	0	2 (1.8)
SUBJECTS WITH ONE OR MORE EVENTS	2 (4.8)	3 (7.1)	8 (7.0)
胃腸障害			
腹痛	0	2 (4.8)	2 (1.8)
上腹部痛	0	1 (2.4)	3 (2.6)
便秘	0	0	1 (0.9)
下痢	2 (4.8)	2 (4.8)	2 (1.8)
消化不良	0	0	1 (0.9)
変色便	0	1 (2.4)	0
胃炎	0	1 (2.4)	1 (0.9)
消化器痛	1 (2.4)	0	0

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
悪心	3 (7.1)	1 (2.4)	6 (5.3)
食道瘻	0	0	1 (0.9)
流涎過多	0	0	1 (0.9)
口蓋垂炎	0	0	1 (0.9)
SUBJECTS WITH ONE OR MORE EVENTS	3 (7.1)	5 (11.9)	15 (13.2)
一般・全身障害および投与部位の状態			
無力症	0	0	1 (0.9)
嚢胞	0	0	1 (0.9)
顔面浮腫	0	0	1 (0.9)
疲労	1 (2.4)	2 (4.8)	3 (2.6)
インフルエンザ様疾患	0	1 (2.4)	0
倦怠感	0	0	1 (0.9)
非心臓性胸痛	0	0	1 (0.9)
浮腫	1 (2.4)	0	1 (0.9)
末梢性浮腫	0	0	2 (1.8)
疼痛	0	0	2 (1.8)
末梢腫脹	1 (2.4)	0	0
発熱	1 (2.4)	0	3 (2.6)
SUBJECTS WITH ONE OR MORE EVENTS	3 (7.1)	2 (4.8)	14 (12.3)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
肝胆道系障害			
脂肪肝	0	1 (2.4)	0
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (2.4)	0
免疫系障害			
過敏症	0	1 (2.4)	0
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (2.4)	0
感染症および寄生虫症			
膿瘍	1 (2.4)	0	0
虫垂炎	0	1 (2.4)	0
体部白癬	0	0	1 (0.9)
ボトリオミセス症	0	0	1 (0.9)
気管支炎	0	0	3 (2.6)
水疱性膿痂疹	0	0	1 (0.9)
蜂巣炎	0	0	1 (0.9)
結膜炎	2 (4.8)	0	0
感染性皮膚炎	0	0	1 (0.9)
憩室炎	0	0	1 (0.9)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
ヘルペス性状湿疹	0	0	2 (1.8)
眼感染	1 (2.4)	0	1 (0.9)
毛包炎	2 (4.8)	2 (4.8)	5 (4.4)
皮膚真菌感染	0	0	1 (0.9)
胃腸炎	1 (2.4)	1 (2.4)	4 (3.5)
消化管感染	0	0	1 (0.9)
陰部ヘルペス	0	0	1 (0.9)
歯肉炎	0	0	1 (0.9)
ヘリコバクター感染	0	0	1 (0.9)
単純ヘルペス	0	2 (4.8)	4 (3.5)
帯状疱疹	0	0	10 (8.8)
麦粒腫	0	0	2 (1.8)
膿痂疹	1 (2.4)	0	8 (7.0)
インフルエンザ	3 (7.1)	0	3 (2.6)
下気道感染	0	1 (2.4)	1 (0.9)
細菌性下気道感染	0	0	1 (0.9)
リンパ管炎	0	1 (2.4)	0
伝染性軟属腫	0	0	2 (1.8)
上咽頭炎	3 (7.1)	5 (11.9)	11 (9.6)
口腔ヘルペス	0	1 (2.4)	2 (1.8)
外耳炎	0	1 (2.4)	1 (0.9)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
爪囲炎	0	1 (2.4)	1 (0.9)
歯冠周囲炎	1 (2.4)	0	0
レンサ球菌性咽頭炎	1 (2.4)	0	3 (2.6)
術後創感染	0	1 (2.4)	0
歯髄炎	0	0	1 (0.9)
腎盂腎炎	0	0	1 (0.9)
膿疱性皮疹	1 (2.4)	2 (4.8)	0
気道感染	0	0	2 (1.8)
鼻炎	0	1 (2.4)	1 (0.9)
敗血症	0	0	1 (0.9)
副鼻腔炎	1 (2.4)	1 (2.4)	3 (2.6)
皮膚感染	3 (7.1)	0	1 (0.9)
ブドウ球菌感染	1 (2.4)	0	0
白癬感染	0	0	1 (0.9)
足部白癬	0	0	1 (0.9)
癜風	0	0	1 (0.9)
歯感染	0	1 (2.4)	2 (1.8)
上気道感染	7 (16.7)	7 (16.7)	26 (22.8)
尿路感染	2 (4.8)	2 (4.8)	6 (5.3)
ウイルス性上気道感染	0	0	2 (1.8)
外陰腟真菌感染	0	0	1 (0.9)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
SUBJECTS WITH ONE OR MORE EVENTS	23 (54.8)	21 (50.0)	68 (59.6)
傷害、中毒および処置合併症			
節足動物咬傷	1 (2.4)	1 (2.4)	0
挫傷	0	0	2 (1.8)
顔面損傷	0	0	1 (0.9)
転倒	0	0	1 (0.9)
靭帯捻挫	0	0	1 (0.9)
四肢損傷	0	0	2 (1.8)
肉離れ	0	0	1 (0.9)
眼窩周囲血腫	0	0	1 (0.9)
外傷後頚部症候群	1 (2.4)	0	0
処置による疼痛	0	1 (2.4)	0
交通事故	1 (2.4)	0	1 (0.9)
皮膚裂傷	0	1 (2.4)	3 (2.6)
サンバーン	0	0	1 (0.9)
歯牙破折	1 (2.4)	0	0
SUBJECTS WITH ONE OR MORE EVENTS	3 (7.1)	3 (7.1)	10 (8.8)
臨床検査			

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
血中ビリルビン増加	0	1 (2.4)	0
血中コレステロール増加	0	0	1 (0.9)
血中クレアチンホスホキナーゼ増加	0	3 (7.1)	7 (6.1)
血中鉄減少	0	0	1 (0.9)
血中テストステロン減少	0	1 (2.4)	0
血中トリグリセリド増加	0	1 (2.4)	1 (0.9)
血中尿酸増加	0	1 (2.4)	0
心雑音	0	0	1 (0.9)
ヘモグロビン減少	0	0	2 (1.8)
肝酵素上昇	0	0	1 (0.9)
赤血球数減少	0	1 (2.4)	0
子宮頚部スミア異常	0	1 (2.4)	0
体重増加	1 (2.4)	0	0
白血球数減少	0	1 (2.4)	0
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.4)	8 (19.0)	12 (10.5)
代謝および栄養障害			
食欲減退	1 (2.4)	0	0
脱水	0	0	1 (0.9)
痛風	0	0	1 (0.9)
高コレステロール血症	0	1 (2.4)	0

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
高トリグリセリド血症	0	0	2 (1.8)
ビタミン B12 欠乏	1 (2.4)	0	0
SUBJECTS WITH ONE OR MORE EVENTS	2 (4.8)	1 (2.4)	4 (3.5)
筋骨格系および結合組織障害			
関節痛	1 (2.4)	0	3 (2.6)
背部痛	1 (2.4)	0	4 (3.5)
筋痙縮	0	1 (2.4)	0
筋骨格系胸痛	1 (2.4)	0	1 (0.9)
筋骨格痛	0	1 (2.4)	1 (0.9)
筋肉痛	0	0	1 (0.9)
頚部痛	0	0	1 (0.9)
変形性関節症	0	0	1 (0.9)
足底筋膜炎	0	0	2 (1.8)
関節リウマチ	0	0	1 (0.9)
肩回旋筋腱板症候群	0	0	1 (0.9)
軟部組織腫脹	0	0	1 (0.9)
腱障害	0	0	1 (0.9)
SUBJECTS WITH ONE OR MORE EVENTS	2 (4.8)	1 (2.4)	14 (12.3)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) 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）			
脂肪腫	0	0	1 (0.9)
単クローン性免疫グロブリン血症	0	0	1 (0.9)
菌状息肉症	0	0	1 (0.9)
脂漏性角化症	0	0	1 (0.9)
皮膚乳頭腫	0	1 (2.4)	3 (2.6)
皮膚有棘細胞癌	0	0	1 (0.9)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (2.4)	7 (6.1)
神経系障害			
注意力障害	0	1 (2.4)	0
浮動性めまい	0	1 (2.4)	2 (1.8)
頭痛	3 (7.1)	3 (7.1)	7 (6.1)
感覚鈍麻	0	0	1 (0.9)
片頭痛	1 (2.4)	0	1 (0.9)
錯感覚	0	0	1 (0.9)
痙攣発作	0	1 (2.4)	0
傾眠	0	0	1 (0.9)
失神	0	0	1 (0.9)
緊張性頭痛	1 (2.4)	0	0

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
SUBJECTS WITH ONE OR MORE EVENTS	5 (11.9)	5 (11.9)	11 (9.6)
精神障害			
不安	0	1 (2.4)	2 (1.8)
錯乱状態	0	1 (2.4)	0
うつ病	0	1 (2.4)	1 (0.9)
不眠症	0	0	2 (1.8)
SUBJECTS WITH ONE OR MORE EVENTS	0	3 (7.1)	4 (3.5)
腎および尿路障害			
ビリルビン尿	0	0	1 (0.9)
血尿	0	0	1 (0.9)
腎結石症	0	0	1 (0.9)
腎症	0	0	1 (0.9)
蛋白尿	0	0	1 (0.9)
腎嚢胞	0	1 (2.4)	0
尿管結石症	0	0	1 (0.9)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (2.4)	6 (5.3)
生殖系および乳房障害			

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
無月経	0	0	1 (0.9)
勃起不全	0	0	1 (0.9)
月経過多	0	0	1 (0.9)
月経前頭痛	0	0	1 (0.9)
精巣痛	0	0	1 (0.9)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	5 (4.4)
呼吸器、胸郭および縦隔障害			
喘息	0	1 (2.4)	1 (0.9)
咳嗽	0	1 (2.4)	3 (2.6)
呼吸困難	0	1 (2.4)	0
鼻出血	0	1 (2.4)	0
喀血	0	0	1 (0.9)
口腔咽頭痛	3 (7.1)	0	0
湿性咳嗽	1 (2.4)	0	0
肺塞栓症	0	0	1 (0.9)
副鼻腔うっ血	0	1 (2.4)	1 (0.9)
睡眠時無呼吸症候群	0	1 (2.4)	0
SUBJECTS WITH ONE OR MORE EVENTS	3 (7.1)	4 (9.5)	7 (6.1)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
皮膚および皮下組織障害			
ざ瘡	4 (9.5)	2 (4.8)	13 (11.4)
光線角化症	0	0	1 (0.9)
水疱	0	0	1 (0.9)
血性水疱	0	0	1 (0.9)
皮膚嚢腫	0	0	2 (1.8)
ざ瘡様皮膚炎	0	1 (2.4)	1 (0.9)
アトピー性皮膚炎	7 (16.7)	5 (11.9)	22 (19.3)
接触皮膚炎	0	1 (2.4)	2 (1.8)
多汗症	0	0	1 (0.9)
間擦疹	1 (2.4)	0	1 (0.9)
ケロイド瘢痕	0	1 (2.4)	0
寝汗	0	2 (4.8)	0
丘疹膿疱性酒さ	0	0	1 (0.9)
光線過敏性反応	0	1 (2.4)	0
ばら色粃糠疹	0	0	1 (0.9)
斑状丘疹状皮疹	0	1 (2.4)	0
酒さ	1 (2.4)	0	1 (0.9)
皮膚不快感	0	0	1 (0.9)
皮膚剥脱	0	1 (2.4)	1 (0.9)
皮膚刺激	0	0	1 (0.9)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
皮膚局面	1 (2.4)	0	0
蕁麻疹	0	0	3 (2.6)
SUBJECTS WITH ONE OR MORE EVENTS	12 (28.6)	13 (31.0)	39 (34.2)
血管障害			
高血圧	1 (2.4)	0	2 (1.8)
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.4)	0	2 (1.8)

NOTE: TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS ANY ADVERSE EVENT WITH AN ONSET DATE ON OR AFTER THE FIRST DOSE OF UPA AND UP TO 30 DAYS AFTER THE LAST DOSE OF UPA. ANY ADVERSE EVENT WITH AN ONSET DATE ON OR AFTER THE FIRST DOSE OF UPA 30 MG RESCUE THERAPHY WILL BE COUNTED INTO UPA 30 MG GROUP. A PATIENT RECEIVING RESCUE THERAPHY AFTER UPA 7.5 MG/15 MG TREATMENT WILL BE COUNTED IN THE DENOMINATORS OF BOTH 7.5 MG/15 MG AND 30 MG DOSE GROUPS.
THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WITHIN EACH TREATMENT GROUP WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.

Program Source Code: [redacted]
相互参照：M16-048 試験 CSR Table 14.3__1.2.1.3

表 4. 投与量ごとの第 1 ピリオド及び第 2 ピリオドの有害事象の 100 人年あたりの発現率：MedDRA のプライマリー器官別大分類及び基本語別（第 1 ピリオド及び第 2 ピリオドの安全性解析対象集団）

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
ANY ADVERSE EVENT	86 (565.8)	109 (526.6)	399 (305.7)
血液およびリンパ系障害			
貧血	0	0	3 (2.3)
内出血発生の増加傾向	0	0	1 (0.8)
リンパ節炎	0	0	1 (0.8)
リンパ節症	1 (6.6)	0	3 (2.3)
リンパ球減少症	0	1 (4.8)	0
好中球減少症	1 (6.6)	2 (9.7)	3 (2.3)
TOTAL EVENTS	2 (13.2)	3 (14.5)	11 (8.4)
心臓障害			
心肺停止	0	0	1 (0.8)
動悸	0	1 (4.8)	0
心膜炎	0	0	1 (0.8)
洞結節機能不全	0	0	1 (0.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
TOTAL EVENTS	0	1 (4.8)	3 (2.3)
先天性、家族性および遺伝性障害			
角膜ジストロフィー	0	0	1 (0.8)
TOTAL EVENTS	0	0	1 (0.8)
耳および迷路障害			
耳痛	0	0	1 (0.8)
回転性めまい	0	1 (4.8)	0
TOTAL EVENTS	0	1 (4.8)	1 (0.8)
内分泌障害			
甲状腺腫	1 (6.6)	0	0
TOTAL EVENTS	1 (6.6)	0	0
眼障害			
白内障	0	0	1 (0.8)
霰粒腫	1 (6.6)	0	0
結膜リンパ管拡張症	0	0	1 (0.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
アレルギー性結膜炎	0	0	1 (0.8)
ドライアイ	0	1 (4.8)	0
眼刺激	0	0	2 (1.5)
虹彩毛様体炎	0	0	1 (0.8)
流涙増加	0	1 (4.8)	1 (0.8)
瞼板腺炎	0	0	1 (0.8)
点状角膜炎	0	1 (4.8)	0
眼瞼腫脹	0	0	1 (0.8)
潰瘍性角膜炎	1 (6.6)	0	0
ぶどう膜炎	0	0	1 (0.8)
霧視	0	0	2 (1.5)
TOTAL EVENTS	2 (13.2)	3 (14.5)	12 (9.2)
胃腸障害			
腹痛	0	2 (9.7)	4 (3.1)
上腹部痛	0	2 (9.7)	3 (2.3)
便秘	0	0	1 (0.8)
下痢	2 (13.2)	5 (24.2)	2 (1.5)
消化不良	0	0	1 (0.8)
変色便	0	1 (4.8)	0

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
胃炎	0	1 (4.8)	1 (0.8)
消化器痛	1 (6.6)	0	0
悪心	3 (19.7)	1 (4.8)	8 (6.1)
食道癆	0	0	1 (0.8)
流涎過多	0	0	1 (0.8)
口蓋垂炎	0	0	1 (0.8)
TOTAL EVENTS	6 (39.5)	12 (58.0)	23 (17.6)
一般・全身障害および投与部位の状態			
無力症	0	0	1 (0.8)
嚢胞	0	0	1 (0.8)
顔面浮腫	0	0	1 (0.8)
疲労	1 (6.6)	3 (14.5)	3 (2.3)
インフルエンザ様疾患	0	3 (14.5)	0
倦怠感	0	0	1 (0.8)
非心臓性胸痛	0	0	1 (0.8)
浮腫	1 (6.6)	0	1 (0.8)
末梢性浮腫	0	0	2 (1.5)
疼痛	0	0	2 (1.5)
末梢腫脹	1 (6.6)	0	0

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
発熱	1 (6.6)	0	3 (2.3)
TOTAL EVENTS	4 (26.3)	6 (29.0)	16 (12.3)
肝胆道系障害			
脂肪肝	0	1 (4.8)	0
TOTAL EVENTS	0	1 (4.8)	0
免疫系障害			
過敏症	0	1 (4.8)	0
TOTAL EVENTS	0	1 (4.8)	0
感染症および寄生虫症			
膿瘍	1 (6.6)	0	0
虫垂炎	0	1 (4.8)	0
体部白癬	0	0	1 (0.8)
ボトリオミセス症	0	0	2 (1.5)
気管支炎	0	0	3 (2.3)
水疱性膿痂疹	0	0	1 (0.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)		UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)		UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)	
蜂巣炎	0		0		1	(0.8)
結膜炎	2	(13.2)	0		0	
感染性皮膚炎	0		0		1	(0.8)
憩室炎	0		0		1	(0.8)
ヘルペス性状湿疹	0		0		2	(1.5)
眼感染	2	(13.2)	0		1	(0.8)
毛包炎	2	(13.2)	2	(9.7)	8	(6.1)
皮膚真菌感染	0		0		3	(2.3)
胃腸炎	1	(6.6)	1	(4.8)	4	(3.1)
消化管感染	0		0		1	(0.8)
陰部ヘルペス	0		0		1	(0.8)
歯肉炎	0		0		1	(0.8)
ヘリコバクター感染	0		0		1	(0.8)
単純ヘルペス	0		2	(9.7)	7	(5.4)
帯状疱疹	0		0		10	(7.7)
麦粒腫	0		0		2	(1.5)
膿痂疹	1	(6.6)	0		8	(6.1)
インフルエンザ	3	(19.7)	0		4	(3.1)
下気道感染	0		1	(4.8)	2	(1.5)
細菌性下気道感染	0		0		1	(0.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS	(E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS	(E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS	(E/100PY)
リンパ管炎	0		1	(4.8)	0	
伝染性軟属腫	0		0		3	(2.3)
上咽頭炎	3	(19.7)	6	(29.0)	16	(12.3)
口腔ヘルペス	0		1	(4.8)	3	(2.3)
外耳炎	0		1	(4.8)	1	(0.8)
爪囲炎	0		1	(4.8)	1	(0.8)
歯冠周囲炎	1	(6.6)	0		0	
レンサ球菌性咽頭炎	1	(6.6)	0		3	(2.3)
術後創感染	0		1	(4.8)	0	
歯髄炎	0		0		1	(0.8)
腎盂腎炎	0		0		1	(0.8)
膿疱性皮疹	1	(6.6)	2	(9.7)	0	
気道感染	0		0		2	(1.5)
鼻炎	0		1	(4.8)	1	(0.8)
敗血症	0		0		1	(0.8)
副鼻腔炎	1	(6.6)	1	(4.8)	3	(2.3)
皮膚感染	4	(26.3)	0		8	(6.1)
ブドウ球菌感染	1	(6.6)	0		0	
白癬感染	0		0		2	(1.5)
足部白癬	0		0		1	(0.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
癜風	0	0	1 (0.8)
歯感染	0	1 (4.8)	2 (1.5)
上気道感染	7 (46.1)	7 (33.8)	47 (36.0)
尿路感染	2 (13.2)	2 (9.7)	8 (6.1)
ウイルス性上気道感染	0	0	2 (1.5)
外陰腟真菌感染	0	0	1 (0.8)
TOTAL EVENTS	33 (217.1)	32 (154.6)	174 (133.3)
傷害、中毒および処置合併症			
節足動物咬傷	1 (6.6)	1 (4.8)	0
挫傷	0	0	2 (1.5)
顔面損傷	0	0	1 (0.8)
転倒	0	0	1 (0.8)
靭帯捻挫	0	0	1 (0.8)
四肢損傷	0	0	2 (1.5)
肉離れ	0	0	1 (0.8)
眼窩周囲血腫	0	0	1 (0.8)
外傷後頚部症候群	1 (6.6)	0	0
処置による疼痛	0	1 (4.8)	0
交通事故	1 (6.6)	0	1 (0.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
皮膚裂傷	0	1 (4.8)	3 (2.3)
サンバーン	0	0	1 (0.8)
歯牙破折	1 (6.6)	0	0
TOTAL EVENTS	4 (26.3)	3 (14.5)	14 (10.7)
臨床検査			
血中ビリルビン増加	0	1 (4.8)	0
血中コレステロール増加	0	0	1 (0.8)
血中クレアチンホスホキナーゼ増加	0	3 (14.5)	8 (6.1)
血中鉄減少	0	0	1 (0.8)
血中テストステロン減少	0	1 (4.8)	0
血中トリグリセリド増加	0	1 (4.8)	1 (0.8)
血中尿酸増加	0	1 (4.8)	0
心雑音	0	0	1 (0.8)
ヘモグロビン減少	0	0	2 (1.5)
肝酵素上昇	0	0	1 (0.8)
赤血球数減少	0	1 (4.8)	0
子宮頚部スミア異常	0	1 (4.8)	0
体重増加	1 (6.6)	0	0
白血球数減少	0	1 (4.8)	0

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
TOTAL EVENTS	1 (6.6)	10 (48.3)	15 (11.5)
代謝および栄養障害			
食欲減退	1 (6.6)	0	0
脱水	0	0	1 (0.8)
痛風	0	0	1 (0.8)
高コレステロール血症	0	1 (4.8)	0
高トリグリセリド血症	0	0	3 (2.3)
ビタミン B12 欠乏	1 (6.6)	0	0
TOTAL EVENTS	2 (13.2)	1 (4.8)	5 (3.8)
筋骨格系および結合組織障害			
関節痛	1 (6.6)	0	3 (2.3)
背部痛	1 (6.6)	0	4 (3.1)
筋痙縮	0	1 (4.8)	0
筋骨格系胸痛	1 (6.6)	0	1 (0.8)
筋骨格痛	0	1 (4.8)	1 (0.8)
筋肉痛	0	0	1 (0.8)
頚部痛	0	0	1 (0.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
変形性関節症	0	0	1 (0.8)
足底筋膜炎	0	0	2 (1.5)
関節リウマチ	0	0	1 (0.8)
肩回旋筋腱板症候群	0	0	1 (0.8)
軟部組織腫脹	0	0	1 (0.8)
腱障害	0	0	1 (0.8)
TOTAL EVENTS	3 (19.7)	2 (9.7)	18 (13.8)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）			
脂肪腫	0	0	1 (0.8)
単クローン性免疫グロブリン血症	0	0	1 (0.8)
菌状息肉症	0	0	1 (0.8)
脂漏性角化症	0	0	1 (0.8)
皮膚乳頭腫	0	1 (4.8)	3 (2.3)
皮膚有棘細胞癌	0	0	1 (0.8)
TOTAL EVENTS	0	1 (4.8)	8 (6.1)
神経系障害			
注意力障害	0	1 (4.8)	0

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
浮動性めまい	0	1 (4.8)	2 (1.5)
頭痛	3 (19.7)	3 (14.5)	7 (5.4)
感覚鈍麻	0	0	1 (0.8)
片頭痛	1 (6.6)	0	1 (0.8)
錯感覚	0	0	1 (0.8)
痙攣発作	0	1 (4.8)	0
傾眠	0	0	1 (0.8)
失神	0	0	1 (0.8)
緊張性頭痛	1 (6.6)	0	0
TOTAL EVENTS	5 (32.9)	6 (29.0)	14 (10.7)
精神障害			
不安	0	1 (4.8)	2 (1.5)
錯乱状態	0	1 (4.8)	0
うつ病	0	1 (4.8)	2 (1.5)
不眠症	0	0	2 (1.5)
TOTAL EVENTS	0	3 (14.5)	6 (4.6)
腎および尿路障害			

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
ビリルビン尿	0	0	1 (0.8)
血尿	0	0	1 (0.8)
腎結石症	0	0	1 (0.8)
腎症	0	0	1 (0.8)
蛋白尿	0	0	1 (0.8)
腎嚢胞	0	1 (4.8)	0
尿管結石症	0	0	1 (0.8)
TOTAL EVENTS	0	1 (4.8)	6 (4.6)
生殖系および乳房障害			
無月経	0	0	1 (0.8)
勃起不全	0	0	1 (0.8)
月経過多	0	0	1 (0.8)
月経前頭痛	0	0	1 (0.8)
精巣痛	0	0	1 (0.8)
TOTAL EVENTS	0	0	5 (3.8)
呼吸器、胸郭および縦隔障害			
喘息	0	1 (4.8)	1 (0.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
咳嗽	0	2 (9.7)	3 (2.3)
呼吸困難	0	1 (4.8)	0
鼻出血	0	1 (4.8)	0
喀血	0	0	1 (0.8)
口腔咽頭痛	3 (19.7)	0	0
湿性咳嗽	1 (6.6)	0	0
肺塞栓症	0	0	1 (0.8)
副鼻腔うっ血	0	1 (4.8)	1 (0.8)
睡眠時無呼吸症候群	0	1 (4.8)	0
TOTAL EVENTS	4 (26.3)	7 (33.8)	7 (5.4)
皮膚および皮下組織障害			
ざ瘡	6 (39.5)	2 (9.7)	14 (10.7)
光線角化症	0	0	1 (0.8)
水疱	0	0	1 (0.8)
血性水疱	0	0	1 (0.8)
皮膚嚢腫	0	0	2 (1.5)
ざ瘡様皮膚炎	0	1 (4.8)	1 (0.8)
アトピー性皮膚炎	9 (59.2)	5 (24.2)	25 (19.2)
接触皮膚炎	0	1 (4.8)	2 (1.5)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
多汗症	0	0	1 (0.8)
間擦疹	1 (6.6)	0	1 (0.8)
ケロイド瘢痕	0	1 (4.8)	0
寝汗	0	2 (9.7)	0
丘疹膿疱性酒さ	0	0	1 (0.8)
光線過敏性反応	0	1 (4.8)	0
ばら色粃糠疹	0	0	1 (0.8)
斑状丘疹状皮疹	0	1 (4.8)	0
酒さ	1 (6.6)	0	1 (0.8)
皮膚不快感	0	0	1 (0.8)
皮膚剥脱	0	1 (4.8)	1 (0.8)
皮膚刺激	0	0	1 (0.8)
皮膚局面	1 (6.6)	0	0
蕁麻疹	0	0	3 (2.3)
TOTAL EVENTS	18 (118.4)	15 (72.5)	58 (44.4)
血管障害			
高血圧	1 (6.6)	0	2 (1.5)
TOTAL EVENTS	1 (6.6)	0	2 (1.5)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)

NOTE: TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS ANY ADVERSE EVENT WITH AN ONSET DATE ON OR AFTER THE FIRST DOSE OF UPA AND UP TO 30 DAYS AFTER THE LAST DOSE OF UPA. ANY ADVERSE EVENT WITH AN ONSET DATE ON OR AFTER THE FIRST DOSE OF UPA 30 MG RESCUE THERAPHY WILL BE COUNTED INTO UPA 30 MG GROUP. A PATIENT RECEIVING RESCUE THERAPHY AFTER UPA 7.5 MG/15 MG TREATMENT WILL BE COUNTED IN THE DENOMINATORS OF BOTH 7.5 MG/15 MG AND 30 MG DOSE GROUPS. E/100PY = EVENTS PER 100 PATIENT-YEARS.

Program Source Code: [redacted]
相互参照：M16-048 試験 CSR Table 14.3__1.2.2.3

表 5. 第 1 ピリオド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 のプライマリー器官別大分類及び基本語別（第 1 ピリオドの安全性解析対象集団）

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	PLACEBO (N=40) n (%)	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=42) n (%)	UPA TOTAL (N=126) n (%)
ANY ADVERSE EVENT	11 (27.5)	17 (40.5)	15 (35.7)	24 (57.1)	56 (44.4)
血液およびリンパ系障害					
貧血	0	0	0	1 (2.4)	1 (0.8)
リンパ節炎	0	0	0	1 (2.4)	1 (0.8)
リンパ球減少症	0	0	1 (2.4)	0	1 (0.8)
好中球減少症	0	1 (2.4)	2 (4.8)	2 (4.8)	5 (4.0)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (2.4)	2 (4.8)	4 (9.5)	7 (5.6)
心臓障害					
心房細動	1 (2.5)	0	0	0	0
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.5)	0	0	0	0
眼障害					
霰粒腫	0	1 (2.4)	0	0	1 (0.8)
ドライアイ	0	0	1 (2.4)	0	1 (0.8)
流涙増加	0	0	0	1 (2.4)	1 (0.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	PLACEBO (N=40) n (%)	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=42) n (%)	UPA TOTAL (N=126) n (%)
点状角膜炎	0	0	1 (2.4)	0	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (2.4)	2 (4.8)	1 (2.4)	4 (3.2)
胃腸障害					
腹痛	1 (2.5)	0	1 (2.4)	1 (2.4)	2 (1.6)
上腹部痛	0	0	1 (2.4)	0	1 (0.8)
下痢	2 (5.0)	2 (4.8)	1 (2.4)	0	3 (2.4)
消化器痛	0	1 (2.4)	0	0	1 (0.8)
悪心	0	2 (4.8)	1 (2.4)	3 (7.1)	6 (4.8)
SUBJECTS WITH ONE OR MORE EVENTS	3 (7.5)	3 (7.1)	2 (4.8)	4 (9.5)	9 (7.1)
一般・全身障害および投与部位の状態					
顔面浮腫	0	0	0	1 (2.4)	1 (0.8)
疲労	0	1 (2.4)	1 (2.4)	1 (2.4)	3 (2.4)
インフルエンザ様疾患	1 (2.5)	0	0	0	0
浮腫	0	0	0	1 (2.4)	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.5)	1 (2.4)	1 (2.4)	2 (4.8)	4 (3.2)
感染症および寄生虫症					

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	PLACEBO (N=40) n (%)	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=42) n (%)	UPA TOTAL (N=126) n (%)
膿瘍	0	1 (2.4)	0	0	1 (0.8)
ボトリオミセス症	0	0	0	1 (2.4)	1 (0.8)
眼感染	0	1 (2.4)	0	0	1 (0.8)
毛包炎	0	2 (4.8)	1 (2.4)	0	3 (2.4)
胃腸炎	1 (2.5)	0	0	0	0
単純ヘルペス	0	0	2 (4.8)	0	2 (1.6)
膿痂疹	0	0	0	2 (4.8)	2 (1.6)
インフルエンザ	0	2 (4.8)	0	0	2 (1.6)
上咽頭炎	0	1 (2.4)	0	1 (2.4)	2 (1.6)
口腔ヘルペス	0	0	1 (2.4)	0	1 (0.8)
腎盂腎炎	0	0	0	1 (2.4)	1 (0.8)
膿疱性皮疹	0	1 (2.4)	2 (4.8)	0	3 (2.4)
鼻炎	1 (2.5)	0	0	1 (2.4)	1 (0.8)
上気道感染	1 (2.5)	4 (9.5)	2 (4.8)	2 (4.8)	8 (6.3)
尿路感染	0	0	0	1 (2.4)	1 (0.8)
ウイルス性上気道感染	0	0	0	1 (2.4)	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	3 (7.5)	11 (26.2)	5 (11.9)	10 (23.8)	26 (20.6)
臨床検査					
血中ビリルビン増加	0	0	1 (2.4)	0	1 (0.8)
血中コレステロール増加	0	0	0	1 (2.4)	1 (0.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	PLACEBO (N=40) n (%)	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=42) n (%)	UPA TOTAL (N=126) n (%)
血中クレアチン増加	1 (2.5)	0	0	0	0
血中クレアチンホスホキナーゼ増加	1 (2.5)	0	2 (4.8)	2 (4.8)	4 (3.2)
血中トリグリセリド増加	0	0	1 (2.4)	1 (2.4)	2 (1.6)
体重増加	0	1 (2.4)	0	0	1 (0.8)
白血球数減少	0	0	1 (2.4)	0	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	2 (5.0)	1 (2.4)	4 (9.5)	3 (7.1)	8 (6.3)
代謝および栄養障害					
食欲減退	0	1 (2.4)	0	0	1 (0.8)
高コレステロール血症	0	0	1 (2.4)	0	1 (0.8)
高トリグリセリド血症	0	0	0	1 (2.4)	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (2.4)	1 (2.4)	1 (2.4)	3 (2.4)
筋骨格系および結合組織障害					
筋肉痛	1 (2.5)	0	0	1 (2.4)	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.5)	0	0	1 (2.4)	1 (0.8)
神経系障害					
注意力障害	0	0	1 (2.4)	0	1 (0.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	PLACEBO (N=40) n (%)	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=42) n (%)	UPA TOTAL (N=126) n (%)
頭痛	0	2 (4.8)	2 (4.8)	1 (2.4)	5 (4.0)
緊張性頭痛	0	1 (2.4)	0	0	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	0	3 (7.1)	2 (4.8)	1 (2.4)	6 (4.8)
精神障害					
錯乱状態	0	0	1 (2.4)	0	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	1 (2.4)	0	1 (0.8)
腎および尿路障害					
血尿	2 (5.0)	0	0	0	0
蛋白尿	1 (2.5)	0	0	0	0
SUBJECTS WITH ONE OR MORE EVENTS	2 (5.0)	0	0	0	0
生殖系および乳房障害					
生殖器病変	1 (2.5)	0	0	0	0
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.5)	0	0	0	0
呼吸器、胸郭および縦隔障害					

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	PLACEBO (N=40) n (%)	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=42) n (%)	UPA TOTAL (N=126) n (%)
咳嗽	0	0	1 (2.4)	0	1 (0.8)
湿性咳嗽	0	1 (2.4)	0	0	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (2.4)	1 (2.4)	0	2 (1.6)
皮膚および皮下組織障害					
ざ瘡	1 (2.5)	1 (2.4)	1 (2.4)	5 (11.9)	7 (5.6)
アトピー性皮膚炎	1 (2.5)	1 (2.4)	1 (2.4)	1 (2.4)	3 (2.4)
ケロイド瘢痕	0	0	1 (2.4)	0	1 (0.8)
寝汗	0	0	1 (2.4)	0	1 (0.8)
斑状丘疹状皮疹	0	0	1 (2.4)	0	1 (0.8)
SUBJECTS WITH ONE OR MORE EVENTS	2 (5.0)	2 (4.8)	5 (11.9)	5 (11.9)	12 (9.5)

NOTE: TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS ANY ADVERSE EVENT WITH AN ONSET DATE ON OR AFTER THE FIRST DOSE OF STUDY DRUG IN PERIOD 1 AND PRIOR TO THE FIRST DOSE OF STUDY DRUG IN PERIOD 2 OR UP TO 30 DAYS AFTER THE LAST DOSE OF STUDY DRUG IF SUBJECT DISCONTINUED STUDY DRUG PREMATURELY FROM PERIOD 1 OF THE STUDY.
THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
EVENT WITH UNKNOWN RELATIONSHIP TO STUDY DRUG IS BEING COUNTED AS HAVING A REASONABLE POSSIBILITY OF BEING STUDY DRUG-RELATED.

Program Source Code: [redacted]

相互参照：M16-048 試験 CSR Table 14.3__1.5.1

表 6. 投与量ごとの第 1 ピリオド及び第 2 ピリオド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 のプライマリ一器官別大分類及び基本語別（第 1 ピリオド及び第 2 ピリオドの安全性解析対象集団）

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
ANY ADVERSE EVENT	18 (42.9)	18 (42.9)	55 (48.2)
血液およびリンパ系障害			
貧血	0	0	2 (1.8)
リンパ節炎	0	0	1 (0.9)
リンパ節症	0	0	1 (0.9)
リンパ球減少症	0	1 (2.4)	0
好中球減少症	1 (2.4)	2 (4.8)	3 (2.6)
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.4)	2 (4.8)	7 (6.1)
心臓障害			
心肺停止	0	0	1 (0.9)
心膜炎	0	0	1 (0.9)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	2 (1.8)
耳および迷路障害			
耳痛	0	0	1 (0.9)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
回転性めまい	0	1 (2.4)	0
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (2.4)	1 (0.9)
眼障害			
霰粒腫	1 (2.4)	0	0
アレルギー性結膜炎	0	0	1 (0.9)
ドライアイ	0	1 (2.4)	0
眼刺激	0	0	1 (0.9)
虹彩毛様体炎	0	0	1 (0.9)
流涙増加	0	0	1 (0.9)
瞼板腺炎	0	0	1 (0.9)
点状角膜炎	0	1 (2.4)	0
眼瞼腫脹	0	0	1 (0.9)
ぶどう膜炎	0	0	1 (0.9)
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.4)	2 (4.8)	4 (3.5)
胃腸障害			
腹痛	0	1 (2.4)	1 (0.9)
上腹部痛	0	1 (2.4)	0
便秘	0	0	1 (0.9)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
下痢	2 (4.8)	1 (2.4)	2 (1.8)
胃炎	0	0	1 (0.9)
消化器痛	1 (2.4)	0	0
悪心	2 (4.8)	1 (2.4)	4 (3.5)
食道瘻	0	0	1 (0.9)
流涎過多	0	0	1 (0.9)
口蓋垂炎	0	0	1 (0.9)
SUBJECTS WITH ONE OR MORE EVENTS	3 (7.1)	2 (4.8)	10 (8.8)
一般・全身障害および投与部位の状態			
顔面浮腫	0	0	1 (0.9)
疲労	1 (2.4)	1 (2.4)	2 (1.8)
浮腫	0	0	1 (0.9)
末梢性浮腫	0	0	1 (0.9)
発熱	0	0	1 (0.9)
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.4)	1 (2.4)	5 (4.4)
感染症および寄生虫症			
膿瘍	1 (2.4)	0	0
体部白癬	0	0	1 (0.9)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) n (%)		UPA 15 MG QD (N=42) n (%)		UPA 30 MG QD (N=114) n (%)	
ボトリオミセス症	0		0		1	(0.9)
気管支炎	0		0		1	(0.9)
水疱性膿痂疹	0		0		1	(0.9)
ヘルペス性状湿疹	0		0		2	(1.8)
眼感染	1	(2.4)	0		1	(0.9)
毛包炎	2	(4.8)	1	(2.4)	4	(3.5)
皮膚真菌感染	0		0		1	(0.9)
消化管感染	0		0		1	(0.9)
歯肉炎	0		0		1	(0.9)
単純ヘルペス	0		2	(4.8)	3	(2.6)
帯状疱疹	0		0		10	(8.8)
膿痂疹	0		0		7	(6.1)
インフルエンザ	2	(4.8)	0		2	(1.8)
伝染性軟属腫	0		0		2	(1.8)
上咽頭炎	1	(2.4)	0		3	(2.6)
口腔ヘルペス	0		1	(2.4)	1	(0.9)
レンサ球菌性咽頭炎	0		0		1	(0.9)
歯髄炎	0		0		1	(0.9)
腎盂腎炎	0		0		1	(0.9)
膿疱性皮疹	1	(2.4)	2	(4.8)	0	
気道感染	0		0		2	(1.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
鼻炎	0	0	1 (0.9)
敗血症	0	0	1 (0.9)
副鼻腔炎	1 (2.4)	0	1 (0.9)
皮膚感染	1 (2.4)	0	1 (0.9)
白癬感染	0	0	1 (0.9)
癜風	0	0	1 (0.9)
上気道感染	4 (9.5)	3 (7.1)	10 (8.8)
尿路感染	0	0	2 (1.8)
ウイルス性上気道感染	0	0	1 (0.9)
SUBJECTS WITH ONE OR MORE EVENTS	13 (31.0)	6 (14.3)	39 (34.2)
傷害、中毒および処置合併症			
処置による疼痛	0	1 (2.4)	0
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (2.4)	0
臨床検査			
血中ビリルビン増加	0	1 (2.4)	0
血中コレステロール増加	0	0	1 (0.9)
血中クレアチンホスホキナーゼ増加	0	2 (4.8)	4 (3.5)
血中トリグリセリド増加	0	1 (2.4)	1 (0.9)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
ヘモグロビン減少	0	0	1 (0.9)
赤血球数減少	0	1 (2.4)	0
体重増加	1 (2.4)	0	0
白血球数減少	0	1 (2.4)	0
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.4)	4 (9.5)	5 (4.4)
代謝および栄養障害			
食欲減退	1 (2.4)	0	0
痛風	0	0	1 (0.9)
高コレステロール血症	0	1 (2.4)	0
高トリグリセリド血症	0	0	1 (0.9)
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.4)	1 (2.4)	2 (1.8)
筋骨格系および結合組織障害			
筋骨格痛	0	1 (2.4)	0
筋肉痛	0	0	1 (0.9)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (2.4)	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）			

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
皮膚乳頭腫	0	1 (2.4)	1 (0.9)
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (2.4)	1 (0.9)
神経系障害			
注意力障害	0	1 (2.4)	0
頭痛	2 (4.8)	2 (4.8)	1 (0.9)
緊張性頭痛	1 (2.4)	0	0
SUBJECTS WITH ONE OR MORE EVENTS	3 (7.1)	2 (4.8)	1 (0.9)
精神障害			
錯乱状態	0	1 (2.4)	0
SUBJECTS WITH ONE OR MORE EVENTS	0	1 (2.4)	0
腎および尿路障害			
ビリルビン尿	0	0	1 (0.9)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	1 (0.9)
生殖系および乳房障害			

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
月経過多	0	0	1 (0.9)
SUBJECTS WITH ONE OR MORE EVENTS	0	0	1 (0.9)
呼吸器、胸郭および縦隔障害			
喘息	0	1 (2.4)	1 (0.9)
咳嗽	0	1 (2.4)	1 (0.9)
湿性咳嗽	1 (2.4)	0	0
SUBJECTS WITH ONE OR MORE EVENTS	1 (2.4)	2 (4.8)	2 (1.8)
皮膚および皮下組織障害			
ざ瘡	1 (2.4)	1 (2.4)	9 (7.9)
ざ瘡様皮膚炎	0	0	1 (0.9)
アトピー性皮膚炎	1 (2.4)	3 (7.1)	5 (4.4)
間擦疹	1 (2.4)	0	1 (0.9)
ケロイド瘢痕	0	1 (2.4)	0
寝汗	0	1 (2.4)	0
丘疹膿疱性酒さ	0	0	1 (0.9)
斑状丘疹状皮疹	0	1 (2.4)	0
皮膚剥脱	0	1 (2.4)	1 (0.9)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) n (%)	UPA 15 MG QD (N=42) n (%)	UPA 30 MG QD (N=114) n (%)
SUBJECTS WITH ONE OR MORE EVENTS	2 (4.8)	8 (19.0)	15 (13.2)

NOTE: TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS ANY ADVERSE EVENT WITH AN ONSET DATE ON OR AFTER THE FIRST DOSE OF UPA AND UP TO 30 DAYS AFTER THE LAST DOSE OF UPA. ANY ADVERSE EVENT WITH AN ONSET DATE ON OR AFTER THE FIRST DOSE OF UPA 30 MG RESCUE THERAPHY WILL BE COUNTED INTO UPA 30 MG GROUP. A PATIENT RECEIVING RESCUE THERAPHY AFTER UPA 7.5 MG/15 MG TREATMENT WILL BE COUNTED IN THE DENOMINATORS OF BOTH 7.5 MG/15 MG AND 30 MG DOSE GROUPS.
THE SUM OF THE TOTAL NUMBER OF SUBJECTS REPORTING EACH OF THE PREFERRED TERMS SHOULD BE GREATER THAN OR EQUAL TO THE SYSTEM ORGAN CLASS TOTAL. A SUBJECT WITHIN EACH TREATMENT GROUP WHO REPORTS TWO OR MORE DIFFERENT PREFERRED TERMS WHICH ARE IN THE SAME SYSTEM ORGAN CLASS IS COUNTED ONLY ONCE IN THE SYSTEM ORGAN CLASS TOTAL.
EVENT WITH UNKNOWN RELATIONSHIP TO STUDY DRUG IS BEING COUNTED AS HAVING A REASONABLE POSSIBILITY OF BEING STUDY DRUG-RELATED.

Program Source Code: [redacted]
相互参照：M16-048 試験 CSR Table 14.3__1.5.2

表 7. 投与量ごとの第 1 ピリオド及び第 2 ピリオド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 のプライマリー器官別大分類及び基本語別（第 1 ピリオド及び第 2 ピリオドの安全性解析対象集団）

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
ANY ADVERSE EVENT	31 (203.9)	50 (241.5)	165 (126.4)
血液およびリンパ系障害			
貧血	0	0	2 (1.5)
リンパ節炎	0	0	1 (0.8)
リンパ節症	0	0	1 (0.8)
リンパ球減少症	0	1 (4.8)	0
好中球減少症	1 (6.6)	2 (9.7)	3 (2.3)
TOTAL EVENTS	1 (6.6)	3 (14.5)	7 (5.4)
心臓障害			
心肺停止	0	0	1 (0.8)
心膜炎	0	0	1 (0.8)
TOTAL EVENTS	0	0	2 (1.5)
耳および迷路障害			

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
耳痛	0	0	1 (0.8)
回転性めまい	0	1 (4.8)	0
TOTAL EVENTS	0	1 (4.8)	1 (0.8)
眼障害			
霰粒腫	1 (6.6)	0	0
アレルギー性結膜炎	0	0	1 (0.8)
ドライアイ	0	1 (4.8)	0
眼刺激	0	0	1 (0.8)
虹彩毛様体炎	0	0	1 (0.8)
流涙増加	0	0	1 (0.8)
瞼板腺炎	0	0	1 (0.8)
点状角膜炎	0	1 (4.8)	0
眼瞼腫脹	0	0	1 (0.8)
ぶどう膜炎	0	0	1 (0.8)
TOTAL EVENTS	1 (6.6)	2 (9.7)	7 (5.4)
胃腸障害			
腹痛	0	1 (4.8)	3 (2.3)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
上腹部痛	0	2 (9.7)	0
便秘	0	0	1 (0.8)
下痢	2 (13.2)	4 (19.3)	2 (1.5)
胃炎	0	0	1 (0.8)
消化器痛	1 (6.6)	0	0
悪心	2 (13.2)	1 (4.8)	5 (3.8)
食道瘻	0	0	1 (0.8)
流涎過多	0	0	1 (0.8)
口蓋垂炎	0	0	1 (0.8)
TOTAL EVENTS	5 (32.9)	8 (38.6)	15 (11.5)
一般・全身障害および投与部位の状態			
顔面浮腫	0	0	1 (0.8)
疲労	1 (6.6)	2 (9.7)	2 (1.5)
浮腫	0	0	1 (0.8)
末梢性浮腫	0	0	1 (0.8)
発熱	0	0	1 (0.8)
TOTAL EVENTS	1 (6.6)	2 (9.7)	6 (4.6)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS	(E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS	(E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS	(E/100PY)
感染症および寄生虫症						
膿瘍	1	(6.6)	0		0	
体部白癬	0		0		1	(0.8)
ボトリオミセス症	0		0		2	(1.5)
気管支炎	0		0		1	(0.8)
水疱性膿痂疹	0		0		1	(0.8)
ヘルペス性状湿疹	0		0		2	(1.5)
眼感染	1	(6.6)	0		1	(0.8)
毛包炎	2	(13.2)	1	(4.8)	7	(5.4)
皮膚真菌感染	0		0		2	(1.5)
消化管感染	0		0		1	(0.8)
歯肉炎	0		0		1	(0.8)
単純ヘルペス	0		2	(9.7)	6	(4.6)
帯状疱疹	0		0		10	(7.7)
膿痂疹	0		0		7	(5.4)
インフルエンザ	2	(13.2)	0		3	(2.3)
伝染性軟属腫	0		0		3	(2.3)
上咽頭炎	1	(6.6)	0		4	(3.1)
口腔ヘルペス	0		1	(4.8)	2	(1.5)
レンサ球菌性咽頭炎	0		0		1	(0.8)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
歯髄炎	0	0	1 (0.8)
腎盂腎炎	0	0	1 (0.8)
膿疱性皮疹	1 (6.6)	2 (9.7)	0
気道感染	0	0	2 (1.5)
鼻炎	0	0	1 (0.8)
敗血症	0	0	1 (0.8)
副鼻腔炎	1 (6.6)	0	1 (0.8)
皮膚感染	1 (6.6)	0	7 (5.4)
白癬感染	0	0	2 (1.5)
癜風	0	0	1 (0.8)
上気道感染	4 (26.3)	3 (14.5)	13 (10.0)
尿路感染	0	0	3 (2.3)
ウイルス性上気道感染	0	0	1 (0.8)
TOTAL EVENTS	14 (92.1)	9 (43.5)	89 (68.2)
傷害、中毒および処置合併症			
処置による疼痛	0	1 (4.8)	0
TOTAL EVENTS	0	1 (4.8)	0

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
臨床検査			
血中ビリルビン増加	0	1 (4.8)	0
血中コレステロール増加	0	0	1 (0.8)
血中クレアチンホスホキナーゼ増加	0	2 (9.7)	5 (3.8)
血中トリグリセリド増加	0	1 (4.8)	1 (0.8)
ヘモグロビン減少	0	0	1 (0.8)
赤血球数減少	0	1 (4.8)	0
体重増加	1 (6.6)	0	0
白血球数減少	0	1 (4.8)	0
TOTAL EVENTS	1 (6.6)	6 (29.0)	8 (6.1)
代謝および栄養障害			
食欲減退	1 (6.6)	0	0
痛風	0	0	1 (0.8)
高コレステロール血症	0	1 (4.8)	0
高トリグリセリド血症	0	0	2 (1.5)
TOTAL EVENTS	1 (6.6)	1 (4.8)	3 (2.3)
筋骨格系および結合組織障害			

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
筋骨格痛	0	1 (4.8)	0
筋肉痛	0	0	1 (0.8)
TOTAL EVENTS	0	1 (4.8)	1 (0.8)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）			
皮膚乳頭腫	0	1 (4.8)	1 (0.8)
TOTAL EVENTS	0	1 (4.8)	1 (0.8)
神経系障害			
注意力障害	0	1 (4.8)	0
頭痛	2 (13.2)	2 (9.7)	1 (0.8)
緊張性頭痛	1 (6.6)	0	0
TOTAL EVENTS	3 (19.7)	3 (14.5)	1 (0.8)
精神障害			
錯乱状態	0	1 (4.8)	0
TOTAL EVENTS	0	1 (4.8)	0

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
腎および尿路障害			
ビリルビン尿	0	0	1 (0.8)
TOTAL EVENTS	0	0	1 (0.8)
生殖系および乳房障害			
月経過多	0	0	1 (0.8)
TOTAL EVENTS	0	0	1 (0.8)
呼吸器、胸郭および縦隔障害			
喘息	0	1 (4.8)	1 (0.8)
咳嗽	0	2 (9.7)	1 (0.8)
湿性咳嗽	1 (6.6)	0	0
TOTAL EVENTS	1 (6.6)	3 (14.5)	2 (1.5)
皮膚および皮下組織障害			
ざ瘡	1 (6.6)	1 (4.8)	10 (7.7)
ざ瘡様皮膚炎	0	0	1 (0.8)
アトピー性皮膚炎	1 (6.6)	3 (14.5)	6 (4.6)

SYSTEM ORGAN CLASS MEDDRA 21.1 PREFERRED TERM	UPA 7.5 MG QD (N=42) (PYS=15.2) EVENTS (E/100PY)	UPA 15 MG QD (N=42) (PYS=20.7) EVENTS (E/100PY)	UPA 30 MG QD (N=114) (PYS=130.5) EVENTS (E/100PY)
間擦疹	1 (6.6)	0	1 (0.8)
ケロイド瘢痕	0	1 (4.8)	0
寝汗	0	1 (4.8)	0
丘疹膿疱性酒さ	0	0	1 (0.8)
斑状丘疹状皮疹	0	1 (4.8)	0
皮膚剥脱	0	1 (4.8)	1 (0.8)
TOTAL EVENTS	3 (19.7)	8 (38.6)	20 (15.3)

NOTE: TREATMENT-EMERGENT ADVERSE EVENT IS DEFINED AS ANY ADVERSE EVENT WITH AN ONSET DATE ON OR AFTER THE FIRST DOSE OF UPA AND UP TO 30 DAYS AFTER THE LAST DOSE OF UPA. ANY ADVERSE EVENT WITH AN ONSET DATE ON OR AFTER THE FIRST DOSE OF UPA 30 MG RESCUE THERAPHY WILL BE COUNTED INTO UPA 30 MG GROUP. A PATIENT RECEIVING RESCUE THERAPHY AFTER UPA 7.5 MG/15 MG TREATMENT WILL BE COUNTED IN THE DENOMINATORS OF BOTH 7.5 MG/15 MG AND 30 MG DOSE GROUPS. E/100PY = EVENTS PER 100 PATIENT-YEARS.
EVENT WITH UNKNOWN RELATIONSHIP TO STUDY DRUG IS BEING COUNTED AS HAVING A REASONABLE POSSIBILITY OF BEING STUDY DRUG-RELATED.

Program Source Code: [redacted]
相互参照：M16-048 試験 CSR Table 14.3__1.5.3

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
心房細動	X			X
食道癆	X	X	X	
心膜炎	X	X	X	
敗血症	X	X	X	

Treatment Group	Age at Study Start	Sex	Race
P1:PLACEBO /P2:ABT-494 30 MG QD	7[redacted]	MALE	WHITE

Medical History	Onset Year
ASTHMA	19[redacted]
DRUG ALLERGIES/REACTIONS: ALLERGIC TO PENICILLIN	19[redacted]
ATOPIC DERMATITIS	20[redacted]
HYPERTENSION: NOT APPLICABLE	20[redacted]
OTHER: PERITONITIS	20[redacted]
EYE DISEASE/DISORDER: LASIK SURGERY	20[redacted]
GOUT: GOUT ATTACK RIGHT GREAT TOE 2013 AND 2016	20[redacted]
OTHER: GANGLIA REMOVED FROM RIGHT FOOT	20[redacted]
OTHER: ACHALASIA	20[redacted]
CHOLELITHIASIS	20[redacted]
EMPHYSEMA/CHRONIC OBSTRUCTIVE PULMONARY DISEASE	20[redacted]
OTHER: ATRIAL FIBRILATION	20[redacted]
OTHER: OBSTRUCTIVE SLEEP APNEA	20[redacted]

Prior Procedures	Procedure Year
SURGERY: APPENDICITIS	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	1 PACK	30	19[redacted]
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	FORMER	2 - 4 drinks

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
PLACEBO		ORAL	QD	[redacted] / 1	[redacted] / 111	111
ABT-494	30 MG	ORAL	QD	[redacted] / 112	[redacted] / 195	84

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
LISINOPRIL	5 mg	QD	Y-M: 20[redacted]
COD-LIVER OIL	30 mL	QD	Y-M: 20[redacted]
IBUPROFEN	400 mg	PRN	Y-M: 20[redacted]
TROXERUTIN	UNKNOWN OTHER: UNKNOWN	QD	Y-M: 20[redacted]
ALOE VERA	UNKNOWN OTHER: UNKNOWN	QD	Y-M: 20[redacted] / -80
BETAMETHASONE	0.05% mg	QD	Y-M: 20[redacted] / -80
ERGOCALCIFEROL	UNKOWN OTHER: UNKNOWN	QD	Y-M: 20[redacted] / -80
EUCERIN	APPLY TO SKIN BID OTHER: UNKNOWN	BID	Y-M: 20[redacted] / -14

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
LISINOPRIL	5 mg	QD	Y-M: 20[redacted]	ONGOING
COD-LIVER OIL	30 mL	QD	Y-M: 20[redacted]	ONGOING
IBUPROFEN	400 mg	PRN	Y-M: 20[redacted]	ONGOING
TROXERUTIN	UNKNOWN OTHER: UNKNOWN	QD	Y-M: 20[redacted]	ONGOING
ERGOCALCIFEROL	UNKOWN OTHER: UNKNOWN	QD	Y-M: 20[redacted] / -80	ONGOING
EUCERIN	APPLY TO SKIN BID OTHER: UNKNOWN	BID	Y-M: 20[redacted] / -14	ONGOING
APIXABAN	5 mg	QD	Y-M: 20[redacted] / 45	ONGOING
PREDNISONE	20 mg	QD	Y-M: 20[redacted] / 194	Y-M: 20[redacted] / 195
ALBUMIN HUMAN	25 mg	PRN	Y-M: 20[redacted] / 195	ONGOING
AMIODARONE	200 mg	BID	Y-M: 20[redacted] / 195	ONGOING
HEPARIN	UNKNOWN OTHER: SET TO MAINTAIN A PTT OF 60	OTHER: CONTINUOUS DRIP	Y-M: 20[redacted] / 195	ONGOING
HYDROMORPHONE	0.2 mg	PRN	Y-M: 20[redacted] / 195	ONGOING
INSULIN	NOT KNOWN OTHER: UNITS	PRN	Y-M: 20[redacted] / 195	ONGOING

METRONIDAZOLE	500 mg	TID	Y-M: 20[redacted]- [redacted] / 195	ONGOING
PANTOPRAZOLE	40 mg	QD	Y-M: 20[redacted]- [redacted] / 195	ONGOING
VERAPAMIL	10 OTHER: MG/HOUR	OTHER: MG/HOUR	Y-M: 20[redacted]- [redacted] / 195	ONGOING
ACETYLSALICYLIC ACID	161 mg	OTHER: ONE TIME DOSE	Y-M: 20[redacted]- [redacted] / 195	Y-M: 20[redacted]-[redacted] / 195
SODIUM CHLORIDE	0.9 %	OTHER: 1 LITER OVER AN HOUR	Y-M: 20[redacted]- [redacted] / 195	Y-M: 20[redacted]-[redacted] / 195
CEFEPIME	2000 mg	BID	Y-M: 20[redacted]- [redacted] / 195	Y-M: 20[redacted]-[redacted] / 209
NOREPINEPHRINE	UNKNOWN		Y-M: 20[redacted]- [redacted] / 195	Y-M: 20[redacted]-[redacted] / 209

Event #1: Serious Adverse Event, Event of Interest - Cardiac Arrhythmias

Event Description	ATRIAL FIBRILLATION
Preferred term	心房細動
AE Onset Date / Rx Day	[redacted]20[redacted] / 45
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
SAE Supplemental Procedure	
[redacted]20[redacted] (RX DAY 45): PACEMAKER PLACEMENT: PACEMAKER PLACED ON [redacted]20[redacted]. PATIENT STAYED OVERNIGHT IN HOSPITAL AND RELEASED ON [redacted]20[redacted] WITHOUT COMPLICATIONS.; [redacted]20[redacted] (RX DAY 168): ABLATION THERAPY: SUBJECT IN SINUS RHYTHYM. NO COMPLICATIONS. RECORDS OF ABLATION REQUESTED. NOT YET RECEIVED.	
AE Stopped Rx Day	332 (137 DAYS AFTER LAST TREATMENT)
Duration of AE	288 DAYS
Severity	Severe
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
Investigator Alternative Etiology	PRE-EXSISTING CONDITION
Relation to Study Drug by AbbVie	NO REASONABLE POSSIBILITY
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT, LIFE THREATENING

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

Event Description	ESOPHAGEAL FISTULA, SEPSIS, PERICARDITIS
Preferred term	食道瘻
AE Onset Date / Rx Day	[redacted]20[redacted] / 194
Age at AE Onset	7[redacted]
Laboratory Testing	
[redacted]20[redacted] (RX DAY 195): Bicarbonate: 18 [0 - 0] MMOL/L; Bilirubin: 26 [0 - 0] UMOL/L; Blood Urea Nitrogen: 12.5	

[0 - 0] MMOL/L; Creatinine: 230 [0 - 0] UMOL/L; Glucose: 10.1 [0 - 0] MMOL/L; Hemoglobin: 136 [0 - 0] G/L; Leukocytes: HIGH [0 - 0] K/UL; Lymphocytes/Leukocytes: 4 [0 - 0] %; NPTST003-CK MB: 2.3 [0 - 0] %; NPTST010-TROPONIN I: 0.03 [0 - 0] NG/ML; Neutrophils/Leukocytes: 87 [0 - 0] %; Platelets: 190 [0 - 0] 10^9/L; Potassium: 5.3 [0 - 0] MMOL/L; Prothrombin Intl. Normalized Ratio: 1.6 [0 - 0] RATIO; Sodium: 137 [0 - 0] MMOL/L; [redacted] (RX DAY 197): Alanine Aminotransferase: 3431 [0 - 55] U/L; Aspartate Aminotransferase: 1355 [5 - 34] U/L; [redacted] (RX DAY 198): Creatinine: 557 [62 - 115] UMOL/L; [redacted] (RX DAY 202): Blood Urea Nitrogen: 24.3 [3.2 - 7.5] MMOL/L; [redacted] (RX DAY 208): Aspartate Aminotransferase: 28 [0 - 0] U/L; [redacted] (RX DAY 209): Blood Urea Nitrogen: 30.7 [0 - 0] MMOL/L; Creatinine: 194 [0 - 0] UMOL/L; Leukocytes: 18.6 [0 - 0] 10^9/L; NPTST009-PTT: 53.2 [0 - 0] SEC

Microbiology

[redacted] (RX DAY 195): BLOOD NPTST005-CULTURE: NEGATIVE-NO GROWTH; OTHER PERICARDIAL FLUID NPTST006-CULTURE OF PERICARDIAL FLUIS: POSITIVE-STREPTOCOCCUS ORALIS (ALSO KNOWN AS MITIS); [redacted] (RX DAY 196): OTHER PERICARDIAL FLUID NPTST005-CULTURE: POSITIVE-STREPTOCOCCUS ORALIS; [redacted] (RX DAY 197): OTHER PERICARDIAL FLUID NPTST005-CULTURE: NEGATIVE-NO GROWTH

SAE Supplemental Procedure

[redacted] (RX DAY 194): CT SCAN: PERICARDIAL EFFUSION; [redacted] (RX DAY 195): CHEST XRAY: NO ACUTE DISEASE; ECG: PACEMAKER RHYTHM OF 83. NO EVIDENCE OF ISCHEMIA AND INFARCTION; ECHOCARDIOGRAM: MODERATE SIZE PERICARDIAL EFFUSION; PERICARDIOCENTESIS: FRANK PUS. +FOR STREPTOCOCCUS ORALIS; ULTRASOUND RIGHT UPPER ABDOMINAL QUADRANT: CHOLELITHIASIS; [redacted] (RX DAY 196): CENTRAL LINE PLACEMENT FOR TEMPORARY DIALYSIS CATHETER: CATHETER PLACED FOR DIALYSIS; DIALYSIS: SUBJECT DIALYZED UNTIL [redacted] WHEN DIALYSIS WAS STOPPED; ESOPHAGRAM WITH GASTROGRAFFIN: ESOPHAGEAL FISTULA WITH ACCUMULATION OF GASTROGRAFFIN IN THE MEDIASTINUM; PERICARDIOCENTESIS: 700ML STRAW COLORED FLUID; [redacted] (RX DAY 197): ENDOSCOPY FOR PLACEMENT OF METAL STENTS TO CLOSE FISTULA: ESPHOGEAL FISTULA/PERFORATION; [redacted] (RX DAY 200): ENDOSCOPY: REMOVAL OF ESPHOGEAL STENT AND REPLACEMENT WITH NEW STENT; [redacted] (RX DAY 209): CHEST TUBE PLACEMENT: LEFT CHEST TUBE PLACED FOR PLEURAL EFFUSION; PICC LINE PLACEMENT: PLACED WITHOUT DIFFICULTY

AE Stopped Rx Day	332 (137 DAYS AFTER LAST TREATMENT)
Duration of AE	139 DAYS
Severity	Severe
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
Investigator Alternative Etiology	ESOPHAGEAL PERFORATION SECONDARY TO ROUTINE SCHEDULED CARDIAC ABLATION RESULTING IN SEPSIS, PERICARDITIS, PLEURAL EFFUSION, AND RENAL FAILURE
Relation to Study Drug by AbbVie	NO REASONABLE POSSIBILITY
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT, LIFE THREATENING, RESULTS IN DEATH

Event #3: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Death

Event Description	ESOPHAGEAL FISTULA, SEPSIS, PERICARDITIS
Preferred term	心膜炎
AE Onset Date / Rx Day	[redacted] / 194
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted] (RX DAY 195): Bicarbonate: 18 [0 - 0] MMOL/L; Bilirubin: 26 [0 - 0] UMOL/L; Blood Urea Nitrogen: 12.5 [0 - 0] MMOL/L; Creatinine: 230 [0 - 0] UMOL/L; Glucose: 10.1 [0 - 0] MMOL/L; Hemoglobin: 136 [0 - 0] G/L; Leukocytes: HIGH [0 - 0] K/UL; Lymphocytes/Leukocytes: 4 [0 - 0] %; NPTST003-CK MB: 2.3 [0 - 0] %; NPTST010-TROPONIN I: 0.03 [0 - 0] NG/ML; Neutrophils/Leukocytes: 87 [0 - 0] %; Platelets: 190 [0 - 0] 10^9/L; Potassium: 5.3 [0 -

0] MMOL/L; Prothrombin Intl. Normalized Ratio: 1.6 [0 - 0] RATIO; Sodium: 137 [0 - 0] MMOL/L; [redacted]20[redacted] (RX DAY 197): Alanine Aminotransferase: 3431 [0 - 55] U/L; Aspartate Aminotransferase: 1355 [5 - 34] U/L; [redacted]20[redacted] (RX DAY 198): Creatinine: 557 [62 - 115] UMOL/L; [redacted]20[redacted] (RX DAY 202): Blood Urea Nitrogen: 24.3 [3.2 - 7.5] MMOL/L; [redacted]20[redacted] (RX DAY 208): Aspartate Aminotransferase: 28 [0 - 0] U/L; [redacted]20[redacted] (RX DAY 209): Blood Urea Nitrogen: 30.7 [0 - 0] MMOL/L; Creatinine: 194 [0 - 0] UMOL/L; Leukocytes: 18.6 [0 - 0] 10^9/L; NPTST009-PTT: 53.2 [0 - 0] SEC

Microbiology

[redacted]20[redacted] (RX DAY 195): BLOOD NPTST005-CULTURE: NEGATIVE-NO GROWTH; OTHER PERICARDIAL FLUID NPTST006-CULTURE OF PERICARDIAL FLUIS: POSITIVE-STREPTOCOCCUS ORALIS (ALSO KNOWN AS MITIS); [redacted]20[redacted] (RX DAY 196): OTHER PERICARDIAL FLUID NPTST005-CULTURE: POSITIVE-STREPTOCOCCUS ORALIS; [redacted]20[redacted] (RX DAY 197): OTHER PERICARDIAL FLUID NPTST005-CULTURE: NEGATIVE-NO GROWTH

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 194): CT SCAN: PERICARDIAL EFFUSION; [redacted]20[redacted] (RX DAY 195): CHEST XRAY: NO ACUTE DISEASE; ECG: PACEMAKER RHYTHM OF 83. NO EVIDENCE OF ISCHEMIA AND INFARCTION; ECHOCARDIOGRAM: MODERATE SIZE PERICARDIAL EFFUSION; PERICARDIOCENTESIS: FRANK PUS. +FOR STREPTOCOCCUS ORALIS; ULTRASOUND RIGHT UPPER ABDOMINAL QUADRANT: CHOLELITHIASIS; [redacted]20[redacted] (RX DAY 196): CENTRAL LINE PLACEMENT FOR TEMPORARY DIALYSIS CATHETER: CATHETER PLACED FOR DIALYSIS; DIALYSIS: SUBJECT DIALYZED UNTIL [redacted]20[redacted] WHEN DIALYSIS WAS STOPPED; ESOPHAGRAM WITH GASTROGRAFFIN: ESOPHAGEAL FISTULA WITH ACCUMULATION OF GASTROGRAFFIN IN THE MEDIASTINUM; PERICARDIOCENTESIS: 700ML STRAW COLORED FLUID; [redacted]20[redacted] (RX DAY 197): ENDOSCOPY FOR PLACEMENT OF METAL STENTS TO CLOSE FISTULA: ESPHOGEAL FISTULA/PERFORATION; [redacted]20[redacted] (RX DAY 200): ENDOSCOPY: REMOVAL OF ESPHOGEAL STENT AND REPLACEMENT WITH NEW STENT; [redacted]20[redacted] (RX DAY 209): CHEST TUBE PLACEMENT: LEFT CHEST TUBE PLACED FOR PLEURAL EFFUSION; PICC LINE PLACEMENT: PLACED WITHOUT DIFFICULTY

AE Stopped Rx Day	332 (137 DAYS AFTER LAST TREATMENT)
Duration of AE	139 DAYS
Severity	Severe
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
Investigator Alternative Etiology	ESOPHAGEAL PERFORATION SECONDARY TO ROUTINE SCHEDULED CARDIAC ABLATION RESULTING IN SEPSIS, PERICARDITIS, PLEURAL EFFUSION, AND RENAL FAILURE
Relation to Study Drug by AbbVie	NO REASONABLE POSSIBILITY
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT, LIFE THREATENING, RESULTS IN DEATH

Event #4: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Death

Event Description	ESOPHAGEAL FISTULA, SEPSIS, PERICARDITIS
Preferred term	敗血症
AE Onset Date / Rx Day	[redacted]20[redacted] / 194
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 195): Bicarbonate: 18 [0 - 0] MMOL/L; Bilirubin: 26 [0 - 0] UMOL/L; Blood Urea Nitrogen: 12.5 [0 - 0] MMOL/L; Creatinine: 230 [0 - 0] UMOL/L; Glucose: 10.1 [0 - 0] MMOL/L; Hemoglobin: 136 [0 - 0] G/L; Leukocytes: HIGH [0 - 0] K/UL; Lymphocytes/Leukocytes: 4 [0 - 0] %; NPTST003-CK MB: 2.3 [0 - 0] %; NPTST010-TROPONIN I: 0.03 [0 - 0] NG/ML; Neutrophils/Leukocytes: 87 [0 - 0] %; Platelets: 190 [0 - 0] 10^9/L; Potassium: 5.3 [0 - 0] MMOL/L; Prothrombin Intl. Normalized Ratio: 1.6 [0 - 0] RATIO; Sodium: 137 [0 - 0] MMOL/L; [redacted]20[redacted] (RX DAY 197): Alanine Aminotransferase: 3431 [0 - 55] U/L; Aspartate Aminotransferase: 1355 [5 - 34] U/L; 05OCT2017 (RX DAY 198): Creatinine: 557 [62 - 115] UMOL/L; [redacted]20[redacted] (RX DAY 202): Blood Urea Nitrogen: 24.3 [3.2 - 7.5]

MMOL/L; [redacted]20[redacted] (RX DAY 208): Aspartate Aminotransferase: 28 [0 - 0] U/L; [redacted]20[redacted] (RX DAY 209): Blood Urea Nitrogen: 30.7 [0 - 0] MMOL/L; Creatinine: 194 [0 - 0] UMOL/L; Leukocytes: 18.6 [0 - 0] 10^9/L; NPTST009-PTT: 53.2 [0 - 0] SEC

Microbiology

[redacted]20[redacted] (RX DAY 195): BLOOD NPTST005-CULTURE: NEGATIVE-NO GROWTH; OTHER PERICARDIAL FLUID NPTST006-CULTURE OF PERICARDIAL FLUIS: POSITIVE-STREPTOCOCCUS ORALIS (ALSO KNOWN AS MITIS); [redacted]20[redacted] (RX DAY 196): OTHER PERICARDIAL FLUID NPTST005-CULTURE: POSITIVE-STREPTOCOCCUS ORALIS; [redacted]20[redacted] (RX DAY 197): OTHER PERICARDIAL FLUID NPTST005-CULTURE: NEGATIVE-NO GROWTH

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 194): CT SCAN: PERICARDIAL EFFUSION; [redacted]20[redacted] (RX DAY 195): CHEST XRAY: NO ACUTE DISEASE; ECG: PACEMAKER RHYTHM OF 83. NO EVIDENCE OF ISCHEMIA AND INFARCTION; ECHOCARDIOGRAM: MODERATE SIZE PERICARDIAL EFFUSION; PERICARDIOCENTESIS: FRANK PUS. +FOR STREPTOCOCCUS ORALIS; ULTRASOUND RIGHT UPPER ABDOMINAL QUADRANT: CHOLELITHIASIS; [redacted]20[redacted] (RX DAY 196): CENTRAL LINE PLACEMENT FOR TEMPORARY DIALYSIS CATHETER: CATHETER PLACED FOR DIALYSIS; DIALYSIS: SUBJECT DIALYZED UNTIL [redacted]20[redacted] WHEN DIALYSIS WAS STOPPED; ESOPHAGRAM WITH GASTROGRAFFIN: ESOPHAGEAL FISTULA WITH ACCUMULATION OF GASTROGRAFFIN IN THE MEDIASTINUM; PERICARDIOCENTESIS: 700ML STRAW COLORED FLUID; [redacted]20[redacted] (RX DAY 197): ENDOSCOPY FOR PLACEMENT OF METAL STENTS TO CLOSE FISTULA: ESPHOGEAL FISTULA/PERFORATION; [redacted]20[redacted] (RX DAY 200): ENDOSCOPY: REMOVAL OF ESPHOGEAL STENT AND REPLACEMENT WITH NEW STENT; [redacted]20[redacted] (RX DAY 209): CHEST TUBE PLACEMENT: LEFT CHEST TUBE PLACED FOR PLEURAL EFFUSION; PICC LINE PLACEMENT: PLACED WITHOUT DIFFICULTY

AE Stopped Rx Day	332 (137 DAYS AFTER LAST TREATMENT)
Duration of AE	139 DAYS
Severity	Severe
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
Investigator Alternative Etiology	ESOPHAGEAL PERFORATION SECONDARY TO ROUTINE SCHEDULED CARDIAC ABLATION RESULTING IN SEPSIS, PERICARDITIS, PLEURAL EFFUSION, AND RENAL FAILURE
Relation to Study Drug by AbbVie	NO REASONABLE POSSIBILITY
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT, LIFE THREATENING, RESULTS IN DEATH

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

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-048

本被験者は米国の 7[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，心房細動を発現した。被験者は元喫煙者（1 箱／日，30 年間）かつ元飲酒者（2～4 杯／日）であり，関連する病歴は喘息，アトピー性皮膚炎，高血圧，心房細動及び慢性閉塞性肺疾患であった。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は心房細動を発現した。20[redacted] 年 [redacted] 月 [redacted] 日，心房細動は消失した。

20[redacted] 年 [redacted] 月 [redacted] 日，スクリーニング時の心電図にて，アーチファクトに加えて心房細動が認められた。被験者は高血圧に対しリシノプリルを使用していた。

入院前，被験者は平衡感覚の喪失を訴えており，かかりつけ医の診療所を受診して安静時心拍数の低下及び心房細動を指摘された。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は入院した。入院時所見は血圧が 160/100 mmHg 及び心拍数が 40 拍/分であった。心電図で心房細動が認められた。臨床検査の結果に異常値はなかった。入院と同日に心臓ペースメーカーを留置した。この時点では血圧が 136/70 mmHg，心拍数が 66 拍/分であり，臨床経過に問題はなかった。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は合併症なく退院した。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は心臓アブレーションを受け，アブレーション後に洞調律化した。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は食道癆，敗血症及び心膜炎のため入院した。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は死亡した（AER # 17P-163-2123801-00 で確認された）。

ELIQUIS が投与された。

The patient's past medications include:

PENICILLIN for UNKNOWN INDICATION

Causality for ABT-494 (Blinded)

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1) Atrial fibrillation (10003658) (Atrial fibrillation (10003658)) [v.21.0] [10003658]

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

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

Dechallenge: Yes

Rechallenge: No rechallenge was done, recurrence is not applicable

Alternative Etiology for ABT-494 (Blinded)

Event of ATRIAL FIBRILLATION

- Investigator: Not applicable.

- AbbVie: History of atrial fibrillation prior to study drug dosing, underlying HTN, chronic lung disease and age.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BLOOD PRESSURE:** 160/100

[redacted] **20[redacted] BLOOD PRESSURE:** 136/70

[redacted] **20[redacted] ECG:** Abnormal rhythm, the patient has a pacemaker installed.

[redacted] **20[redacted] CHEST X-RAY:** No evidence of complication following pacemaker placement, stable possible left lower pulmonary nodule noted (further testing suggested).

[redacted] **20[redacted] EKG:** Atrial Fibrillation

[redacted] **20[redacted] EKG:** Atrial fibrillation, mild left atrial enlargement, borderline left ventricular hypertrophy with normal ejection fraction, mild aortic sclerosis, and trace mitral and trace tricuspid regurgitation.

[redacted] **20[redacted] HEART RATE:** 40 BPM

[redacted] **20[redacted] HEART RATE:** 66 BPM

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-048

本被験者は米国の 7[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，食道癆，敗血症及び心膜炎を発現して死亡した。被験者は元喫煙者（1 箱／日，30 年間）かつ元飲酒者（4 杯超／日）であり，関連する病歴は本態性高血圧症，腹膜炎，心房細動，胆石症，慢性閉塞性肺疾患，肺気腫，閉塞性睡眠時無呼吸，洞不全症候群及び肥満であった。

20[redacted] 年[redacted] 月[redacted] 日，被験者は食道癆，敗血症及び心膜炎を発現した。20[redacted] 年[redacted] 月[redacted] 日，被験者は死亡した。報告された死因は食道癆，敗血症及び心膜炎であった。検死の実施有無は不明である。

被験者は 20[redacted] 年[redacted] 月[redacted] 日に心房細動及び心拍数低下（ペースメーカー留置）を発現していた（AER #17P-163-1971961-00）。

20[redacted] 年[redacted] 月[redacted] 日，被験者は心臓アブレーションを受けた。20[redacted] 年[redacted] 月[redacted] 日の朝，被験者は放散しない胸痛のため救急治療室を受診した。トロポニンは正常値であり，ペースメーカーによる心調律が確認され，心虚血ではないと判断された。胸部コンピュータ断層撮影検査で少量の心嚢液貯留が認められた。被験者は Dilaudid を投与され，帰宅した。

20[redacted] 年 [redacted] 月 [redacted] 日の夕方，被験者は持続する胸部絞扼感及び息切れとともに頭部ふらふら感，疲労及び錯乱を発現し，救急治療室を再受診した。心筋梗塞は否定されたが，被験者は低血圧（収縮期血圧 80 mmHg 台）であった。ベッドサイドの心エコー検査で中等量から多量の心嚢液貯留が認められた。被験者は集中治療室に入室し，心膜穿刺が計画された。精査の結果，被験者は心臓アブレーション処置中の食道穿孔により敗血症を来たしたと診断された。急性腎不全及びトランスアミナーゼ上昇が認められ，敗血症性ショックの所見と一致した。

20[redacted] 年 [redacted] 月 [redacted] 日，昇圧薬投与及び透析のルートとして内頚静脈カテーテルが留置された。入院期間中，敗血症による腎不全に対し間欠的透析が行われた。20[redacted] 年 [redacted] 月 [redacted] 日，食道瘻／穿孔を塞ぐための 1 度目の内視鏡下金属ステント留置が行われた。入院経過中，ステントの移動や再漏出のため，複数回の上部消化管ステント留置術が行われた。20[redacted] 年 [redacted] 月 [redacted] 日を最後に入院期間中の透析を終了した。

20[redacted] 年 [redacted] 月 [redacted] 日，末梢挿入中心静脈カテーテルとともに，持続する中等度の左側胸水に対し胸腔ドレーンが留置された。同日，被験者は三次救急医療機関に転院した。20[redacted] 年 [redacted] 月 [redacted] 日，被験者は試験を中止した。

被験者の妻によれば，20[redacted] 年 [redacted] 月に被験者はリハビリテーション施設に転院し，緩やかに改善した。20[redacted] 年 [redacted] 月に治験実施施設が被験者の妻から入手した情報によれば，被験者はホスピスに転院し，20[redacted] 年 [redacted] 月 [redacted] 日に死亡した。被験者は長期入院の後，ホスピスに入院した。治験実施施設は死亡診断書を入手できなかった。

LEVOPHED，DILAUDID，KCENTRA，中心静脈栄養，アスピリン，塩化ナトリウム（静注用生理食塩液），AMIODARONE，PREDNISONE，PANTOPRAZOLE，アルブミン，VERAPAMIL，インスリン，LASIX，FLAGYL，CEFEPIME，バンコマイシン及びヘパリンが投与された。

Causality for ABT-494 (Blinded)

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1) Esophageal fistula (10065851) (Oesophageal fistula (10065835)) [v.20.1] [10065851]

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

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

Dechallenge: Not Applicable

2) Sepsis (10040047) (Sepsis (10040047)) [v.20.1] [10040047]

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

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

Dechallenge: Not Applicable

3) Pericarditis (10034484) (Pericarditis (10034484)) [v.20.1] [10034484]

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

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

Dechallenge: Not Applicable

Alternative Etiology for ABT-494 (Blinded)

Event of ESOPHAGEAL FISTULA, SEPSIS, PERICARDITIS

- Investigator: Esophageal perforation secondary to routine scheduled cardiac ablation resulting in sepsis, pericarditis, pleural effusion, and renal failure.

- AbbVie: Event is more likely a complication from routine scheduled cardiac ablation procedure.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ABSOLUTE LYMPHOCYTE:** 0.4 K/UL (normal 1.0 to 3.2)

[redacted] **20[redacted] ABSOLUTE NEUTROPHIL COUNT:** 9.7 L/UL (normal 1.7 to 7.6)

[redacted] **20[redacted] ABSOLUTE NEUTROPHIL COUNT:** 17.9 L/UL (normal 1.7 to 7.6)

[redacted] **20[redacted] ABSOLUTE NEUTROPHIL COUNT:** 7.5 L/UL (normal 1.7 to 7.6)

[redacted] **20[redacted] ABSOLUTE NEUTROPHIL COUNT:** 8.8 L/UL (normal 1.7 to 7.6)

[redacted] **20[redacted] ABSOLUTE NEUTROPHIL COUNT:** 12.8 L/UL (normal 1.7 to 7.6)

[redacted] **20[redacted] ALANINE AMINOTRANSFERASE:** 3431 uL (normal 0 to 55)

[redacted] **20[redacted] ALT:** 145 no units

[redacted] **20[redacted] ASPARTATE AMINOTRANSFERASE:** 1355 U/L (normal 5 to 34)

[redacted] **20[redacted] AST:** 120 no units

[redacted] **20[redacted] BICARBONATE:** 18 MMOL/L

[redacted] **20[redacted] BILIRUBIN:** 1.5 mg/dL

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

[redacted] **20[redacted] BLOOD UREA NITROGEN:** 50 mg/dL (normal 9 to 21)

[redacted] **20[redacted] BLOOD UREA NITROGEN:** 66 mg/dL (normal 9 to 21)

[redacted] **20[redacted] BLOOD UREA NITROGEN:** 50 mg/dL (normal 9 to 21)

[redacted] **20[redacted] BLOOD UREA NITROGEN:** 68 mg/dL (normal 9 to 21)

[redacted] **20[redacted] BUN:** 35 mg/dL

[redacted] **20[redacted] CHEST X-RAY:** no acute disease

[redacted] **20[redacted] CK MB:** 2.3 %

[redacted] **20[redacted] CREATININE:** 2.6 mg/dL

[redacted] **20[redacted] CREATININE:** 2.6 mg/dL (normal 0.7 to 1.3)

[redacted] **20[redacted] CREATININE:** 6.3 mg/dL (normal 0.7 to 1.3)

[redacted] **20[redacted] CREATININE:** 5.8 mg/dL (normal 0.7 to 1.3)

[redacted] **20[redacted] CREATININE:** 6.5 mg/dL (normal 0.7 to 1.3)

[redacted] **20[redacted] CREATININE:** 4.9 mg/dL (normal 0.7 to 1.3)

[redacted] **20[redacted] CREATININE:** 5.4 mg/dL (normal 0.7 to 1.3)

[redacted] **20[redacted] CT SCAN:** pericardial effusion, small pneumopericardium, Cholelithiasis, no sighs of cholecystitis

[redacted] **20[redacted] CT SCAN CHEST:** small pericardial effusion, no signs of pneumonia, pulmonary embolism or cardiac abnormality; cholelithiasis noted

[redacted] **20[redacted] ECG:** pacemaker rhythm of 83. No evidence of ischemia and infarction

[redacted] **20[redacted] ECHOCARDIOGRAM:** mild left atrial enlargement, borderline LVH, normal EF, mild aortic sclerosis

[redacted] **20[redacted] ECHOCARDIOGRAM:** moderate size pericardial effusion, no echocardiographic evidence for cardiac tamponade. EF normal range of 50% to 55% with no segmental wall motion abnormalities. No significant valvular abnormalities seen and no evidence of endocarditis.

[redacted] **20[redacted] EGD:** Placement of metal stents to close fistula

[redacted] **20[redacted] EGD:** stent removed due to dislodging

Unknown date EGD #3: 3rd EGD: clipping of the proximal and distal stent

Unknown date EGD #4: stents placed in a partially overlapping manner: good results

[redacted] **20[redacted] EKG:** Pacemaker rhythm of 83. No evidence of ischemia and infarction

Unknown date ESOPHAGRAM: confirmation of leak after 3rd EGD stent clipping

[redacted] **20[redacted] GASTROGRAPHIN SWALLOW CT SCAN:** esophageal fistula with accumulation of gastrographin in the mediastinum; confirmed esophageal pericardial connection with possible pleural connection

[redacted] **20[redacted] GASTROGRAPHIN SWALLOW CT SCAN:** confirmation of a gastrographin behind the stentwith possible extravasation into the pericardium

[redacted] **20[redacted] GLUCOSE:** 182 mg/dL

[redacted] **20[redacted] HEMOGLOBIN:** 13.6 G/DL

[redacted] **20[redacted] INR:** 1.6 Ratio

[redacted] **20[redacted] LYMPHOCYTES:** 4 %

[redacted] **20[redacted] NEUTROPHIL COUNT:** 87 % (normal 44 to 74)

[redacted] **20[redacted] NEUTROPHIL COUNT:** 93 % (normal 44 to 74)

[redacted] **20[redacted] NEUTROPHIL COUNT:** 87 % (normal 44 to 74)

[redacted] **20[redacted] NEUTROPHIL COUNT:** 85 % (normal 44 to 74)

[redacted] **20[redacted] NEUTROPHIL COUNT:** 88 % (normal 44 to 74)

[redacted] **20[redacted] PERICARDIAL FLUID CULTURE:** Positive: strep mitis

[redacted] **20[redacted] PERICARDIAL FLUID CULTURE:** Positive: strep mitis

[redacted] **20[redacted] PERICARDIAL FLUID CULTURE:** Negative

[redacted] **20[redacted] PERICARDIOCENTESIS:** 700 ml of straw color turbid fluid

[redacted] **20[redacted] PLATELET COUNT:** 190 K/UL

[redacted] **20[redacted] POTASSIUM:** 5.3 MMOL/L

[redacted] **20[redacted] SODIUM:** 137 MMOL/L

[redacted] **20[redacted] SYSTOLIC BLOOD PRESSURE:** In the 70s and 80s.

[redacted] **20[redacted] SYSTOLIC BLOOD PRESSURE:** 144 mmHg

[redacted] **20[redacted] TEE:** no pericardial effusion, normal EF and moderately dilated left atrium

[redacted] 20[redacted] **TROPONIN I:** 0.028 NG/ML

[redacted] 20[redacted] **ULTRASOUND (RIGHT UPPER ABDOMINAL QUADRANT):** cholelithiasis

[redacted] 20[redacted] **ULTRASOUND GALLBLADDER:** likely cholecystitis with thickened gallbladder wall and stone in neck of gallbladder

[redacted] 20[redacted] **WBC:** 11.1 K/UL

[redacted] 20[redacted] **WBC:** 19.3 K/UL (normal 3.6 to 10.2)

[redacted] 20[redacted] **WBC:** 8.6 K/UL (normal 3.6 to 10.2)

[redacted] 20[redacted] **WBC:** 7.0 K/UL (normal 3.6 to 10.2)

[redacted] 20[redacted] **WBC:** 10.3 K/UL (normal 3.6 to 10.2)

[redacted] 20[redacted] **WBC:** 14.7 K/UL (normal 3.6 to 10.2)

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
血中クレアチンホスホキナーゼ増加				X
心肺停止	X		X	

Treatment Group	Age at Study Start	Sex	Race
P1:ABT-494 30 MG QD /P2:PLACEBO /P2 RESCUE:ABT-494 30 MG QD	6[redacted]	FEMALE	WHITE

Medical History	Onset Year
ATOPIC DERMATITIS	19[redacted]
ATOPIC DERMATITIS	19[redacted]
OTHER: POST MENOPAUSAL	20[redacted]
OTHER: BASAL CELL CARCINOMA RIGHT TEMPLE	20[redacted]
OTHER: SQUAMOUS CELL CARCINOMA EXCISION RIGHT FOREARM	20[redacted]
OTHER: SQUAMOUS CELL CARCINOMA EXCISION LEFT SHOULDER	20[redacted]
OTHER: ACTINIC KERATOSIS	20[redacted]
ASTHMA	20[redacted]
HYPERTENSION	20[redacted]

Prior Procedures	Procedure Year
INCREASED CREATINE PHOSPHOKINASE: FRACTIONATED LAB TEST	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 drinks

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
ABT-494	30 MG	ORAL	QD	[redacted]20[redacted] / 1	[redacted]20[redacted] / 113	113
PLACEBO		ORAL	QD	[redacted]20[redacted] / 114	[redacted]20[redacted] / 166	53
ABT-494	30 MG	ORAL	QD	[redacted]20[redacted] / 167	[redacted]20[redacted] / 391	225

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
SALBUTAMOL	90 mg	PRN	Y-M: 19[redacted]
MULTIVITAMIN	NO SPECIFIC DOSAGE mg	BID	Y-M: 19[redacted]
CALCIUM	600 mg	OTHER: 3 XWK	Y-M: 20[redacted]
HYDROXYZINE	25 mg	PRN	Y-M: 20[redacted]

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
SALBUTAMOL	90 mg	PRN	Y-M: 19[redacted]	ONGOING
MULTIVITAMIN	NO SPECIFIC DOSAGE mg	BID	Y-M: 19[redacted]	ONGOING
CALCIUM	600 mg	OTHER: 3 XWK	Y-M: 20[redacted]	ONGOING
HYDROXYZINE	25 mg	PRN	Y-M: 20[redacted]	ONGOING

Event #1: Event of Interest - CPK Elevation

Event Description	ELEVATED CK
Preferred term	血中クレアチンホスホキナーゼ増加
AE Onset Date / Rx Day	[redacted]20[redacted] / 58
Age at AE Onset	6[redacted]

Laboratory Testing
NOT APPLICABLE

Microbiology
NOT APPLICABLE

SAE Supplemental Procedure
NOT APPLICABLE

AE Stopped Rx Day	64
Duration of AE	7 DAYS
Severity	Mild
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
Investigator Alternative Etiology	NOT APPLICABLE
Relation to Study Drug by AbbVie	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Serious Adverse Event, Death

Event Description	CARDIOPULMONARY ARREST
Preferred term	心肺停止
AE Onset Date / Rx Day	[redacted]20[redacted] / 393 (2 DAYS AFTER LAST TREATMENT)
Age at AE Onset	6[redacted]

Laboratory Testing
NOT REPORTED

Microbiology
NOT REPORTED
SAE Supplemental Procedure
NOT REPORTED

AE Stopped Rx Day	393 (2 DAYS AFTER LAST TREATMENT)
Duration of AE	1 DAY
Severity	Severe
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
Investigator Alternative Etiology	NOT REPORTED
Relation to Study Drug by AbbVie	NO REASONABLE POSSIBILITY
Discontinued Study Drug Due to the Event	NO
SAE Criteria	LIFE THREATENING, RESULTS IN DEATH

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

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M16-048

本被験者は米国の 6[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が投与され，心肺停止を発現して死亡した。被験者は閉経した女性で，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高血圧であった。

20[redacted] 年 [redacted] 月 [redacted] 日，被験者は心肺停止を発現し，同日に死亡した。報告された死因は心肺停止であった。検死は実施されなかった。

死亡診断書によれば，死亡した場所は自宅，死因は心肺停止であった。本報告では，その他の情報は提供されなかった。

Causality for ABT-494 (Blinded)

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1) Cardiopulmonary arrest (10007644) (Cardio-respiratory arrest (10007617)) [v.20.1] [10007644]

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

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

Dechallenge: Not Applicable

Alternative Etiology for ABT-494 (Blinded)

Event of CARDIOPULMONARY ARREST

- Investigator: Not applicable

- AbbVie: Risk factors include hypertension, age and post menopausal status

非重篤な有害事象

被験者はクレアチンホスホキナーゼの軽度増加を発現した。症状はなく，先行又は併発した有害事象はなかった。関連する病歴はなかった。治験責任医師によれば，クレアチンホスホキナーゼの増加の原因は特定されず，本事象に対し治療は行われなかった。

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
アトピー性皮膚炎	X	X		
皮膚感染	X	X		

Treatment Group	Age at Study Start	Sex	Race
P1:ABT-494 7.5 MG QD	2[redacted]	FEMALE	WHITE

Medical History	Onset Year
ATOPIC DERMATITIS	19[redacted]
OTHER: TONSILLITIS	19[redacted]
ATOPIC DERMATITIS	20[redacted]
OTHER: ACNE	20[redacted]
ASTHMA	20[redacted]
OTHER: SCOLIOSIS	20[redacted]
PNEUMONIA	20[redacted]
DEPRESSION	20[redacted]
OTHER: ALLERGY TO ANIMAL DANDER	20[redacted]
OTHER: ALLERGY TO DUST MITES	20[redacted]
OTHER: ALLERGY TO POLLEN	20[redacted]
OTHER: ANXIETY	20[redacted]
OTHER: CONTACT DERMATITIS	20[redacted]

Prior Procedures	Procedure Year
Not reported.	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	0.5 PACK	1	20[redacted]
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2 drinks

Study Drug Administration

Study Drug	Dose/Units	Route	Frequency	First Dose Date/Day	Last Dose Date/Day	Duration (Days)
ABT-494	7.5 MG	ORAL	QD	[redacted]20[redacted] /	[redacted]20[redacted] / 17	17

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
BUDESONIDE W/FORMOTEROL FUMARATE	200 OTHER: MCG	PRN	Y-M: 20[redacted]
NORMENSAL	500/35 OTHER: MCG/MCG	QD	Y-M: 20[redacted]
DESVENLAFAXINE	100 mg	QD	Y-M: 20[redacted] / -66
DIPROBASE	1 OTHER: APPLICATION	BID	Y-M: 20[redacted] / -66
FEXOFENADINE	10 mg	QD	Y-M: 20[redacted] / -66
OTHER EMOLLIENTS AND PROTECTIVES	2 OTHER: APPLICATION	BID	Y-M: 20[redacted] / -62

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	200 OTHER: MCG	PRN	Y-M: 20[redacted]	ONGOING
NORMENSAL	500/35 OTHER: MCG/MCG	QD	Y-M: 20[redacted]	ONGOING
DIPROBASE	1 OTHER: APPLICATION	BID	Y-M: 20[redacted] / -66	ONGOING
FEXOFENADINE	10 mg	QD	Y-M: 20[redacted] / -66	ONGOING
DESVENLAFAXINE	100 mg	QD	Y-M: 20[redacted] / -66	Y-M: 20[redacted] / 17
OTHER EMOLLIENTS AND PROTECTIVES	2 OTHER: APPLICATION	BID	Y-M: 20[redacted] / -62	ONGOING
PROMETHAZINE	10 mg	QD	Y-M: 20[redacted] / 16	Y-M: 20[redacted] / 21
CEFALEXIN	500 mg	QID	Y-M: 20[redacted] / 16	Y-M: 20[redacted] / 27
PREDNISONE	50 mg	QD	Y-M: 20[redacted] / 17	Y-M: 20[redacted] / 19
ESCITALOPRAM	60 mg	QD	Y-M: 20[redacted] / 18	ONGOING
MULTIVITAMIN	1 OTHER: TABLET	QD	Y-M: 20[redacted] / 18	ONGOING
MIDAZOLAM	2.5 mg	OTHER: STAT	Y-M: 20[redacted] / 18	Y-M: 20[redacted] / 18
MORPHINE	2.5 mg	OTHER: STAT	Y-M: 20[redacted] / 18	Y-M: 20[redacted] / 18
MORPHINE	8.5 mg	OTHER: STAT	Y-M: 20[redacted] / 18	Y-M: 20[redacted] / 18
ONDANSETRON	4 mg	OTHER: STAT	Y-M: 20[redacted] / 18	Y-M: 20[redacted] / 18
OXYCODONE	5 mg	PRN	Y-M: 20[redacted] / 18	Y-M: 20[redacted] / 19
BETAMETHASONE	1 OTHER: APPLICAITON	BID	Y-M: 20[redacted] / 18	Y-M: 20[redacted] / 21
IBUPROFEN	200 mg	PRN	Y-M: 20[redacted] / 18	Y-M: 20[redacted] / 21

LORATADINE	10 mg	BID	Y-M: 20[redacted]-[redacted] / 18	Y-M: 20[redacted]-[redacted] / 21
PARACETAMOL	1000 mg	PRN	Y-M: 20[redacted]-[redacted] / 18	Y-M: 20[redacted]-[redacted] / 21
PARAFFIN	1 OTHER: APPLICATION	QID	Y-M: 20[redacted]-[redacted] / 18	Y-M: 20[redacted]-[redacted] / 21
PARAFFIN, LIQUID	1 OTHER: APPLICATION	QD	Y-M: 20[redacted]-[redacted] / 18	Y-M: 20[redacted]-[redacted] / 21
POTASSIUM PERMANGANATE	1 OTHER: APPLICATION	QD	Y-M: 20[redacted]-[redacted] / 18	Y-M: 20[redacted]-[redacted] / 21
PREDNISONE	25 mg	QD	Y-M: 20[redacted]-[redacted] / 20	Y-M: 20[redacted]-[redacted] / 21

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

Event Description	SKIN INFECTION EXACERBATION ATOPIC DERMATITIS
Preferred term	アトピー性皮膚炎
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	21 (4 DAYS AFTER LAST TREATMENT)
Duration of AE	9 DAYS
Severity	Moderate
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
Investigator Alternative Etiology	CONTACT DERMATITIS
Relation to Study Drug by AbbVie	REASONABLE POSSIBILITY
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	SKIN INFECTION EXACERBATION ATOPIC DERMATITIS
Preferred term	皮膚感染
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	21 (4 DAYS AFTER LAST TREATMENT)
Duration of AE	9 DAYS
Severity	Moderate
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY

Investigator Alternative Etiology	CONTACT DERMATITIS
Relation to Study Drug by AbbVie	REASONABLE POSSIBILITY
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: M16-048

本被験者はオーストラリアの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が投与され，皮膚感染増悪アトピー性皮膚炎を発現した。関連する病歴はアトピー性皮膚炎，喘息，動物のふけアレルギー，イエダニアレルギー，花粉アレルギー及び接触皮膚炎であった。

20[redacted]年[redacted]月[redacted]日，被験者は皮膚感染増悪アトピー性皮膚炎を発現した。20[redacted]年[redacted]月[redacted]日，皮膚感染増悪アトピー性皮膚炎は消失した。

20[redacted]年[redacted]月[redacted]日，被験者は入院した。入院記録及び身体所見：皮膚感染によるアトピー性皮膚炎の急性増悪症状及び徴候として発赤，そう痒症，浮腫及び疼痛を認めた。本事象の臨床経過中，被験者は入院し，治療として油浴，抗生物質（経口），副腎皮質ステロイド（外用及び経口）及び鎮痛療法が用いられた。皮膚炎は寛解したが，依然として中等度から高度のアトピー性皮膚炎が持続していた。20[redacted]年[redacted]月[redacted]日，被験者は退院した。

イブプロフェン，アセトアミノフェン，PREDNISONE，ENDONE，モルヒネ，オンダンセトロン，PARAFFIN WHITE SOFT LIQUID 50%-50%，500G 軟膏，POTASSIUM PERMANGANATE CRYSTALS，流動パラフィン，セファレキシン，PHENERGAN，ロラタジン（CLARATYNE），ミダゾラム及びベタメタゾンジプロピオン酸エステル（DIPROSONE）が投与された。

Causality for ABT-494 (Blinded)

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1) Dermatitis atopic aggravated (10012439) (Dermatitis atopic (10012438)) [v.19.1] [10012439]

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

2) Skin infection (10040872) (Skin infection (10040872)) [v.19.1] [10040872]

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

Alternative Etiology for ABT-494 (Blinded)

Event of SKIN INFECTION EXACERBATION ATOPIC DERMATITIS

- Investigator: Contact dermatitis

- **AbbVie:** N/A

M16-045 試験（投与 16 週時）

治験の標題： 中等症から重症の青少年及び成人アトピー性皮膚炎患者におけるウパダシチニブの第 III 相，ランダム化，プラセボ対照，二重盲検試験	
治験実施施設： 24 ヵ国（アルゼンチン，オーストラリア，ボスニア・ヘルツェゴビナ，ブルガリア，カナダ，中国，コロンビア，クロアチア，デンマーク，エストニア，フィンランド，フランス，ドイツ，イタリア，日本，マレーシア，ニュージーランド，ルーマニア，ロシア連邦，スイス，トルコ，ウクライナ，英国及び米国［プエルトリコ］）の 151 施設	
治験調整医師： [redacted], MD, PhD	
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 8 月 13 日 最後の被験者の最終来院日：20[redacted] 年 [redacted] 月 [redacted] 日（投与 16 週時）	開発のフェーズ：III
目的： 全身療法の対象となる中等症から重症の青少年及び成人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有効性及び安全性を評価する。 16 週間の二重盲検投与期では，ウパダシチニブ 30 mg 及び 15 mg を 1 日 1 回（以下「QD」）投与時の安全性及び有効性をプラセボ投与時と比較する。盲検継続投与期では，二重盲検投与期を完了した中等症から重症の青少年及び成人アトピー性皮膚炎患者を対象として，ウパダシチニブ 30 mg 及び 15 mg QD 投与時の長期的な安全性，忍容性及び有効性を評価する。	
被験者数（計画時と解析時）： 計画時：810 名，解析時：847 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る，3）外用薬が効果不十分であったことを示す記録がある，又はアトピー性皮膚炎に対する全身療法の記録がある，4）以下の疾患活動性基準をすべて満たす：スクリーニング及びベースライン来院時に湿疹面積重症度指数（以下「EASI」）スコア 16 以上，スクリーニング及びベースライン来院時に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，スクリーニング及びベースライン来院時にアトピー性皮膚炎病変の体表面積 10%以上，及び毎日の最悪のかゆみの数値評価尺度（以下「NRS」）のベースライン来院時の週平均値 4 以上	
治験方法： 本試験（継続中）は全身療法の対象である中等症から重症の青少年（12～17 歳）及び成人（18～75 歳）アトピー性皮膚炎患者を対象として，ウパダシチニブ単独投与の有効性及び安全性を評価する，第 III 相，ランダム化，二重盲検，プラセボ対照，多施設共同試験であった。 本試験は，主試験（青少年及び成人を対象）及び青少年サブスタディ（青少年を対象）で構成された。主試験及び青少年サブスタディのいずれも，35 日間のスクリーニング期間，16 週間の二重盲検投与期及び最長で投与 136 週までの盲検継続投与期から構成され，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。	

主試験の適格性基準を満たした被験者を，1：1：1 の割合でウパダシチニブ 30 mg，ウパダシチニブ 15 mg 又はプラセボの QD 経口投与にランダム化した。主試験への目標例数の登録が完了後，引き続き追加試験（青少年サブスタディ）への青少年被験者の登録を行い，青少年被験者の登録数が試験全体（主試験 + 青少年サブスタディ）で計 180 名になるまで継続することとした。本項では，主試験の投与 16 週時までの中間解析の結果を示す。青少年サブスタディは，被験者登録を継続中である。 主試験では，ベースライン疾患重症度（中等症［vIGA-AD スコア 3］ / 重症［vIGA-AD スコア 4］），地理的地域（米国・プエルトリコ・カナダ / 日本 / 中国 / その他）及び年齢（青少年［12～17 歳］ / 成人［18～75 歳］）による層別ランダム化を行った。投与 16 週時に，プラセボ群の被験者を 1：1 の割合で盲検継続投与期におけるウパダシチニブ 15 mg 又は 30 mg の QD 経口投与に再度割り付けた。また，投与 16 週時までの EASI 50 レスポンダー（はい / いいえ），地理的地域（米国・プエルトリコ・カナダ / 中国 / 日本 / その他）及び年齢（青少年［12～17 歳］ / 成人［18～75 歳］）による層別ランダム化を行った。最初にウパダシチニブ群にランダム化された被験者には，盲検継続投与期も継続して同じ用量のウパダシチニブを投与することとした。投与 4 週時来院以降，医学的に必要と判断された特定のパラメータに合致した場合，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可能であった。
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] 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] 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：最長で投与 136 週まで
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：

有効性：

共主要評価項目は，投与 16 週時に EASI スコアのベースラインからの 75%以上の低下（以下「EASI 75」）を達成した被験者の割合，及び投与 16 週時の 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）した被験者の割合であった。

米国食品医薬品局（以下「FDA」）及び欧州医薬品庁（以下「EMA」）の規制に対応する重要な副次評価項目は以下のとおりであった。

- 投与 16 週時に最悪のかゆみの 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
- 投与 16 週時に EASI スコアのベースラインからの 90%以上の低下を達成した被験者の割合
- 投与 16 週時の最悪のかゆみの NRS のベースラインからの変化率（EMA のみ）
- 投与 4 週時に最悪のかゆみの 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（FDA のみ）
- 投与 16 週時の EASI スコアのベースラインからの変化率（EMA のみ）
- 投与 2 週時に EASI 75 を達成した被験者の割合
- 投与 1 週時に最悪のかゆみの 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
- 投与 16 週時の患者評価による湿疹重症度スコア（以下「POEM」）がベースラインから 4 以上改善（低下）した被験者の割合（EMA のみ）
- スクリーニング時に 16 歳以上であった被験者のうち，投与 16 週時に皮膚科関連 QOL 評価指標（以下「DLQI」）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（EMA のみ）
- 投与 2 日目に最悪のかゆみの 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（ウパダシチニブ 30 mg vs. プラセボ）
- 投与 3 日目に最悪のかゆみの 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（ウパダシチニブ 15 mg vs. プラセボ）
- EASI の臨床的に意義のある悪化を特徴とする再燃（ベースライン時の EASI スコアが 65.4 以下であった被験者における EASI スコアのベースラインからの 6.6 以上の上昇）が二重盲検投与期に認められた被験者の割合
- 投与 16 週時のアトピー性皮膚炎の重症度分類スコア（以下「SCORAD」）のベースラインからの変化率（EMA のみ）
- ベースライン時の一般外来患者用不安抑うつテスト-不安（以下「HADS-A」）が 8 以上又は一般外来患者用不安抑うつテスト-抑うつ（以下「HADS-D」）が 8 以上であった被験者のうち，投与 16 週時に HADS-A 8 未満及び HADS-D 8 未満を達成した被験者の割合（EMA のみ）
- 投与 16 週時にアトピー性皮膚炎の影響の評価尺度（以下「ADerm-IS」）睡眠ドメインスコアがベースラインから 12（臨床的に意義のある最小変化量［以下「MCID」］）以上改善（低下）した被験者の割合
- 投与 16 週時にアトピー性皮膚炎症状の尺度（以下「ADerm-SS」）の皮膚の痛みスコアがベースラインから 4（MCID）以上改善（低下）した被験者の割合
- 投与 16 週時に ADerm-SS の 7 項目合計症状スコアがベースラインから 28（MCID）以上改善（低下）した被験者の割合
- 投与 16 週時に ADerm-IS の精神状態ドメインスコアがベースラインから 11（MCID）以上改善（低下）した被験者の割合
- 投与 16 週時に ADerm-IS の日常活動ドメインスコアがベースラインから 14（MCID）以上改善（低下）した被験者の割合
- 投与 16 週時に EASI スコアのベースラインからの 100%以上の低下を達成した被験者の割合
- スクリーニング時に 16 歳以上であった被験者のうち，投与 16 週時に DLQI スコア 0 又は 1 を達成した被験者の割合（EMA のみ）

薬物動態：
ベースライン後の規定の来院時に，血漿中ウパダシチニブ濃度測定用の血液検体を採取した。

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（血液学的検査，血液生化学検査，尿検査）及び製品苦情のデータを評価した。

統計手法：
有効性：
主試験の ITT 集団（以下「ITT_M 集団」）は，主試験のすべてのランダム化された被験者から構成され，すべての有効性解析に用いた。ITT_M 集団の被験者の解析は，主試験でランダム化された投与群に基づいて実施した。二重盲検投与期にプラセボ群にランダム化され，盲検継続投与期に移行しなかった被験者は，盲検継続投与期の解析に含めなかった。主試験の治験実施計画書に適合した解析対象集団（以下「PP_M 集団」）は，ITT_M 集団の部分集団であり，有効性の共主要評価項目に影響を与え得る治験実施計画書からの重大な逸脱があった被験者を除外した。有効性の共主要評価項目の感度分析は，PP_M 集団を用いて実施した。

薬物動態：
被験者ごとの血漿中ウパダシチニブ濃度を一覧表にし，適切な統計手法を用いて要約した。

安全性：
主試験の二重盲検投与期（16 週間）の安全性解析対象集団は，主試験の二重盲検投与期に治験薬投与を 1 回以上受けたすべてのランダム化された被験者から構成された。主試験の全ウパダシチニブ投与集団は，主試験でウパダシチニブ投与を 1 回以上受けたすべての被験者から構成された。主試験の盲検継続投与期の安全性解析対象集団は，主試験の盲検継続投与期に治験薬投与を 1 回以上受けたすべてのランダム化された被験者から構成された（主試験の盲検継続投与期の安全性解析対象集団は，臨床検査の評価にのみ用いた）。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。有害事象が発現した被験者の数及び割合を，ICH 国際医薬用語集（以下「MedDRA」）の器官別大分類及び基本語を用いて投与群ごとに示した。また，重篤な有害事象の要約，並びに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の有害事象の要約も示した。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を一覧表に示した。各来院時のバイタルサイン，身体検査及び臨床検査の変化を要約した。

要約 / 結論：
有効性の結果：
中等症から重症のアトピー性皮膚炎患者を対象とした第 III 相試験である本試験では，二重盲検投与期（二重盲検，プラセボ対照，16 週間）での，ウパダシチニブ 30 mg 及び 15 mg のプラセボに対する優越性が共主要評価項目及び副次評価項目により一貫して示された。
共主要評価項目は，投与 16 週時に EASI 75 を達成した被験者の割合，及び投与 16 週時の 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 グレード以上改善した被験者の割合であった。共主要評価項目は，ウパダシチニブ群でプラセボ群と比較して統計学的に有意に高かった。また，様々な皮膚症状の改善，並びにかゆみ及びアトピー性皮膚炎の他の影響の改善の基準値に関する副次評価項目でプラセボ群と比較して有意な差が認められた。
ウパダシチニブ 30 mg 群及びウパダシチニブ 15 mg 群では，プラセボ群と比較してかゆみが有意に減少し，投与 16 週時に最悪のかゆみの NRS がベースラインから 4 以上改善した被験者の割合は，ウパダシチニブ群の方が高かった。プラセボ群と比較して，ウパダシチニブ 30 mg 群及びウパダシチニブ 15 mg 群では早期に反応が認められ，投与 2 週時に EASI 75 を達成した被験者の割合は有意に高かった。また，最悪のかゆみの NRS がベースラインから 4 以上改善した被験者の割合は，ウパダシチニブ 30 mg 群では投与 2 日目，ウパダシチニブ 15 mg 群で