SUPPLEMENTAL MATERIALS

Long-Term Safety and Efficacy of Upadacitinib or Adalimumab in Patients With Rheumatoid Arthritis: Results Through 3 Years From the SELECT-COMPARE Study

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Supplemental Table 1. Demographic and Clinical Characteristics of Patients at Baseline

Characteristic	PBO + MTX (N = 651)	UPA 15 mg QD + MTX (N = 651)	ADA 40 mg EOW + MTX (N = 327)
Female, no. (%)	512 (79)	521 (80)	259 (79)
RA duration since diagnosis, years	8 ± 8	8 ± 8	8 ± 8
Age, years	54 ± 12	54 ± 12	54 ± 12
RF+ and/or ACPA+, no. (%)	571 (88)	566 (87)	288 (88)
MTX dose, mg/week	16.8 ± 3.8	17.0 ± 4.2	17.1 ± 3.8
Prior bDMARD exposure, no. (%)	63 (10)	54 (8)	34 (10)
Oral glucocorticoid use, no. (%)	392 (60)	388 (60)	202 (62)
Dose, mg*	6.3 ± 2.4	6.2 ± 2.3	6.5 ± 2.4
TJC68	26 ± 14	26 ± 15	26 ± 15
SJC66	16 ± 9	17 ± 10	16 ± 9
PtGA (100-mm VAS)	64 ± 21	64 ± 22	66 ± 21
PhGA (100-mm VAS)	66 ± 18	66 ± 17	65 ± 18
Pain (100-mm VAS)	65 ± 21	66 ± 21	66 ± 21
hsCRP, mg/liter	18 ± 22	18 ± 22	20 ± 22
DAS28(CRP) (scale 0-10)	5.8 ± 0.9	5.8 ± 1.0	5.9 ± 1.0
DAS28(ESR) (scale 0-10)	6.5 ± 1.0	6.4 ± 1.0	6.5 ± 1.0
CDAI (scale 0-76)	40 ± 13	40 ± 13	40 ± 13
HAQ-DI (scale 0-3)	1.6 ± 0.6	1.6 ± 0.6	1.6 ± 0.6
mTSS (scale 0-448)	36 ± 52	34 ± 50	35 ± 47
Erosion score (scale 0-168)	17 ± 27	17 ± 26	15 ± 23
JSN score (scale 0-280)	19 ± 26	18 ± 25	19 ± 26
Duration of morning stiffness, minutes	142 ± 170	142 ± 188	146 ± 185
FACIT-F score (scale 0-52)	27 ± 11	27 ± 11	26 ± 11
SF-36 PCS score (scale 0-100)	33 ± 7	33 ± 7	32 ± 7

Except where indicated otherwise, values are the mean ± SD. *Based on prednisone or equivalent daily dose. ADA, adalimumab; ACPA+, anti-cyclic citrullinated peptide positive; bDMARD, biologic disease-modifying antirheumatic drug; CDAI, clinical disease activity index; DAS28(CRP), 28-joint disease activity score based on C-reactive protein (CRP); DAS28(ESR), DAS28 using erythrocyte sedimentation rate; EOW, every other week; FACIT-F, Functional Assessment of Chronic Illness Therapy Fatigue; SF-36 PCS, 36-item Short Form physical component summary; HAQ-DI, Health Assessment Questionnaire Disability Index; JSN, joint space narrowing; mTSS, modified total Sharp/van der Heijde score; MTX, methotrexate; PBO, placebo; PhGA, physician global assessment of disease activity; PtGA, patient global assessment of disease activity; QD, once daily; RA, rheumatoid arthritis; RF+, rheumatoid factor positive; SJC66, swollen joint count based on 66 joints; TJC68, tender joint count based on 68 joints; UPA, upadacitinib; VAS, visual analog scale.

Supplementary Table 2. Most Common Treatment-Emergent Adverse Events Reported Through 156 Weeks (E/100 PY)

Type*	UPA 15 mg QD + MTX (N = 1417; PY = 2795.8) Events (E/100 PY) [95% CI]	ADA 40 mg EOW + MTX (N = 579; PY = 947.8) Events (E/100 PY) [95% CI]
Upper respiratory tract infection	231 (8.3) [7.2, 9.4]	53 (5.6) [7.2, 9.4]
Urinary tract infection	212 (7.6) [6.6, 8.7]	74 (7.8) [6.1, 9.8]
Nasopharyngitis	206 (7.4) [6.4, 8.4]	61 (6.4) [4.9, 8.3]
Alanine aminotransferase increased	164 (5.9) [5.0, 6.8]	38 (4.0) [5.1, 8.5]
Bronchitis	160 (5.7) [4.9, 6.7]	63 (6.6) [5.1, 8.5]
Blood creatine phosphokinase increased	132 (4.7) [4.0, 5.6]	16 (1.7) [1.0, 2.7]
Aspartate aminotransferase increased	129 (4.6) [3.9, 5.5]	25 (2.6) [2.7, 5.3]
Hypertension	117 (4.2) [3.5, 5.0]	36 (3.8) [2.7, 5.3]
Leukopenia	91 (3.3) [2.6, 4.0]	13 (1.4) [0.7, 2.3]
Rheumatoid arthritis†	89 (3.2) [2.6, 3.9]	64 (6.8) [5.2, 8.6]

*Based on the MedDRA 22.0 Preferred term. †Refers to a worsening of the underlying disease. Data include all patients receiving upadacitinib or adalimumab, including rescue groups, with assignment based on drug exposure at the time of event.
ADA, adalimumab; EOW, every other week; MTX, methotrexate; QD, once daily; UPA, upadacitinib.

Supplemental Table 3. History of Patients with Adjudicated Major Adverse Cardiovascular Events

Treatment Group	MACE Type(s)	Relevant Medical History [Age at Start of Study]
UPA	CV death	Diabetes mellitus, hypothyroidism, prednisolone use [73 yo]
UPA	MI	Hypertension, smoker, prior MI event, prednisone use [68 yo]
UPA	CV death	Hypertension, former smoker [77 yo]
UPA	MI	Hypertension, obesity (BMI 58.2), dyslipidemia, diabetes mellitus, smoker [42 yo]
UPA	MI	Pre-existing cardiac condition, obesity (BMI 35.5), diabetes mellitus, [53 yo]
UPA	MI	Hyperlipidemia, former smoker, prednisone use [51 yo]
UPA	CV death (PE)	Hypertension, obesity (BMI 36.1), former smoker, trauma, recent prolonged immobilization due to fall, prednisone use [74 yo]
UPA	Stroke	Patent foramen ovale, hypercholesterolemia, smoker [39 yo]
UPA	Stroke	Hypertension, obesity (BMI 42.8), diabetes mellitus, smoker, prednisolone use [55 yo]
UPA	CV death	Hypertension, obesity (BMI 41.8), diabetes mellitus, prednisone use [58 yo]
ADA	CV death	Pre-existing cardiac condition, history of chronic bronchitis, obesity (BMI 34), hypertension, diabetes mellitus [66 yo]
ADA	Stroke	Hypertension, smoker, thrombolysis therapy for prior PE, hydrocortisone use [57 yo]
ADA	Stroke	Hypertension, hyperlipidemia [71 yo]
ADA	Stroke	Hypertension, obesity (BMI 43.9), hyperlipidemia, diabetes mellitus, atrial fibrillation, prednisone use [59 yo]

ADA, adalimumab; MACE, major adverse cardiovascular event; PE, pulmonary embolism; UPA, upadacitinib.

Supplemental Table 4. History of Patients with Adjudicated Venous Thromboembolism Events

Treatment Group	VTE Type(s)	Relevant Medical History [Age at Start of Study]
UPA	DVT	Obesity (BMI 39.7), methylprednisolone use [34 yo]
UPA	DVT	Dyslipidemia, hypertension, obesity (BMI 35.5) former smoker, recent history of prolonged sitting, prednisone use [51 yo]
UPA	DVT, PE	Obesity (BMI 31.2), recent lower extremity trauma, prednisone use [36 yo]
UPA	PE	Hypertension, obesity (BMI 31.2), recent hospitalization [44 yo]
UPA	PE	Trauma, obesity (BMI 36.1), recent immobilization due to fall, prednisone use [74 yo]
UPA	DVT, PE	Prior history of VTE, smoker, prednisone use [51 yo]
UPA	PE	Hypertension, obesity (BMI 37.5), former smoker, family history of PE [63 yo]
UPA	PE	Hypertension, former smoker, obesity (BMI 37.5), methylprednisolone use [65 yo]
UPA	DVT	Hypertension, obesity (BMI 41.8), prior history of PE, hyperlipidemia, sleep apnea, prednisone use [67 yo]
ADA	PE	Hypertension, obesity (BMI 32.0), concurrent event of worsening dyspnea, methylprednisolone use [52 yo]
ADA	DVT	Hypertension, lower extremity varicose veins, sedentary lifestyle, methylprednisolone use [61 yo]
ADA	PE	Hypertension, obesity (BMI 64.0), former smoker, atrial fibrillation, pulmonary fibrosis, prolonged immobilization due to hospitalization, prednisone use [60 yo]
ADA	PE	Hypertension, smoker, prolonged immobilization [57 yo]
ADA	PE	Hypertension, obesity (BMI 41.3), former smoker, hyperlipidemia, family history of PE [69 yo]

ADA, adalimumab; DVT, deep vein thrombosis; PE, pulmonary embolism; VTE, venous thromboembolism; UPA, upadacitinib.

Supplemental Table 5. Treatment-Emergent Serious or Opportunistic Infections Among Patients with Grade 4 Lymphopenia

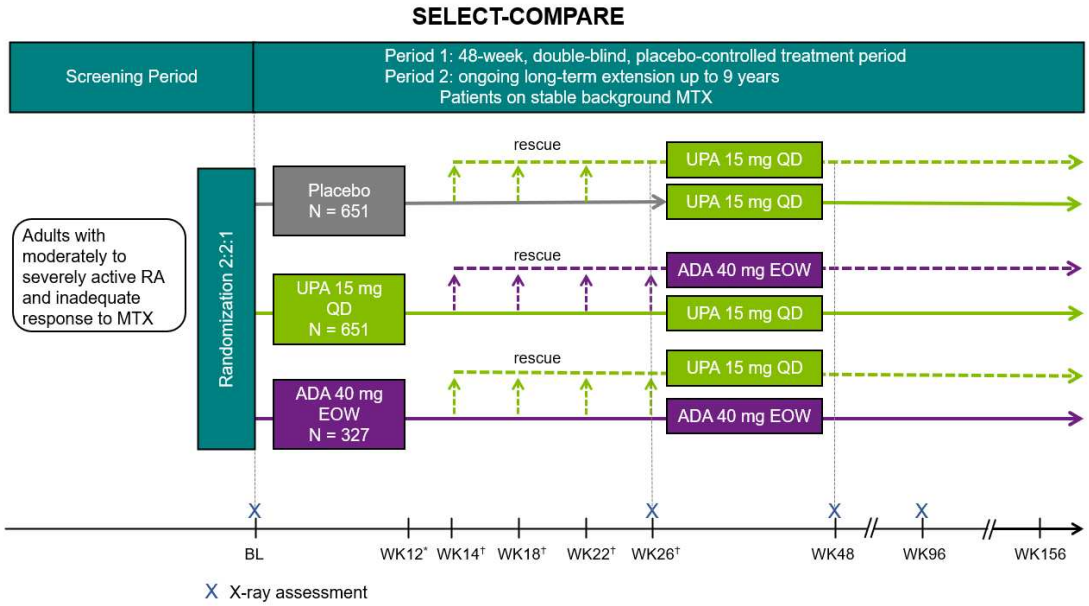
Lab parameter	UPA 15 mg QD + MTX (N = 41) Events (%)	ADA 40 mg EOW + MTX (N = 3) Events (%)
Lymphopenia (Grade 4)*		
Serious Infection†	3 (7.3)	1 (33.3)
Opportunistic Infection	0	0

*Grade 4 lymphopenia included all patients with a total lymphocyte count of <500 cell/mm^3. †Serious infections reported on upadacitinib included a single case each of pneumonia, influenza, and respiratory tract infection; one case of pneumonia was reported on adalimumab. Data include all patients receiving upadacitinib or adalimumab, including rescue groups, with assignment based on drug exposure at the time of event. ADA, adalimumab; EOW, every other week; MTX, methotrexate; QD, once daily; UPA, upadacitinib.

Supplemental Table 6. Categorial Data Points Plotted Through 156 Weeks (NRI)

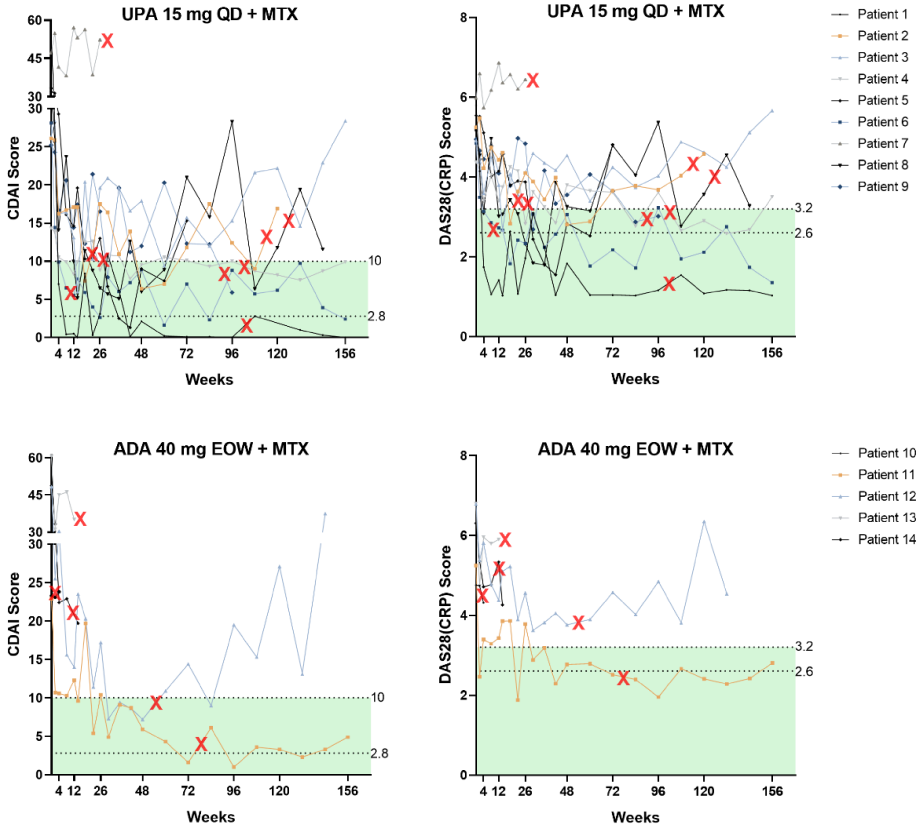
	Weeks													
n/N (%)	**4**	**8**	**12**	**26**	**48**	**60**	**72**	**84**	**96**	**108**	**120**	**132**	**144**	**156**
CDAI ≤10														
UPA 15 mg QD	117/651 (18.0)	213/651 (32.7)	263/651 (40.4)	343/651 (52.7)	299/651 (45.9)	299/651 (45.9)	294/651 (45.2)	290/651 (44.5)	285/651 (43.8)	276/651 (42.4)	277/651 (42.5)	271/651 (41.6)	265/651 (40.7)	257/651 (39.5)
ADA 40 mg EOW	46/327 (14.1)	91/327 (27.8)	98/327 (30.0)	125/327 (38.2)	107/327 (32.7)	107/327 (32.7)	104/327 (31.8)	99/327 (30.3)	98/327 (30.0)	100/327 (30.6)	99/651 (30.3)	102/327 (31.2)	96/327 (29.4)	96/327 (29.4)
CDAI ≤2.8														
UPA 15 mg QD	27/651 (4.1)	61/651 (9.4)	87/651 (13.4)	150/651 (23.0)	166/651 (25.5)	160/651 (24.6)	183/651 (28.1)	176/651 (27.0)	177/651 (27.2)	163/651 (25.0)	169/651 (26.0)	170/651 (26.1)	159/651 (24.4)	159/651 (24.4)
ADA 40 mg EOW	7/327 (2.1)	15/327 (4.6)	25/327 (7.6)	45/327 (13.8)	55/327 (16.8)	49/327 (15.0)	54/327 (16.5)	56/327 (17.1)	53/327 (16.2)	53/327 (16.2)	51/327 (15.6)	55/327 (16.8)	60/327 (18.3)	54/327 (16.5)
DAS28(CRP) ≤3.2														
UPA 15 mg QD	166/651 (25.5)	249/651 (38.2)	293/651 (45.0)	356/651 (54.7)	297/651 (45.6)	286/651 (43.9)	293/651 (45.0)	283/651 (43.5)	282/651 (43.3)	284/651 (43.6)	275/651 (42.2)	269/651 (41.3)	253/651 (38.9)	241/651 (37.0)
ADA 40 mg EOW	57/327 (17.4)	93/327 (28.4)	94/327 (28.7)	126/327 (38.5)	105/327 (32.1)	99/327 (30.3)	96/327 (29.4)	93/327 (28.4)	93/327 (28.4)	104/327 (31.8)	95/327 (29.1)	95/327 (29.1)	90/327 (27.5)	85/327 (26.0)
DAS28(CRP) <2.6														
UPA 15 mg QD	90/651 (13.8)	153/651 (23.5)	187/651 (28.7)	266/651 (40.9)	243/651 (37.3)	247/651 (37.9)	259/651 (39.8)	256/651 (39.3)	242/651 (37.2)	238/651 (36.6)	242/651 (37.2)	236/651 (36.3)	215/651 (33.0)	211/651 (32.4)
ADA 40 mg EOW	32/327 (9.8)	53/327 (16.2)	59/327 (18.0)	88/327 (26.9)	87/327 (26.6)	79/327 (24.2)	83/327 (25.4)	83/327 (25.4)	78/327 (23.9)	84/327 (25.7)	79/327 (24.2)	79/327 (24.2)	76/327 (23.2)	71/327 (21.7)
ACR20														
UPA 15 mg QD	343/651 (52.7)	424/651 (65.1)	450/651 (69.1)	436/651 (67.0)	328/651 (50.4)	316/651 (48.5)	305/651 (46.9)	308/651 (47.3)	306/651 (47.0)	302/651 (46.4)	298/651 (45.8)	288/651 (44.2)	271/651 (41.6)	271/651 (41.6)
ADA 40 mg EOW	149/327 (45.6)	190/327 (58.1)	206/327 (63.0)	187/327 (57.2)	116/327 (35.5)	117/327 (35.8)	110/327 (33.6)	107/327 (32.7)	109/327 (33.3)	108/327 (33.0)	106/327 (32.4)	107/327 (32.7)	103/327 (31.5)	98/327 (30.0)
ACR50														
UPA 15 mg QD	136/651 (20.9)	227/651 (34.9)	288/651 (44.2)	349/651 (53.6)	284/651 (43.6)	279/651 (42.9)	279/651 (42.9)	282/651 (43.3)	277/651 (42.5)	262/651 (40.2)	270/651 (41.5)	253/651 (38.9)	240/651 (36.9)	249/651 (38.2)
ADA 40 mg EOW	47/327 (14.4)	96/327 (29.4)	93/327 (28.4)	137/327 (41.9)	101/327 (30.9)	101/327 (30.9)	93/327 (28.4)	96/327 (29.4)	95/327 (29.1)	94/327 (28.7)	88/327 (26.9)	94/327 (28.7)	91/327 (27.8)	87/327 (26.6)
ACR70														
UPA 15 mg QD	60/651 (9.2)	114/651 (17.5)	162/651 (24.9)	224/651 (34.4)	225/651 (34.6)	226/651 (34.7)	227/651 (34.9)	223/651 (34.3)	223/651 (34.3)	219/651 (33.6)	217/651 (33.3)	209/651 (32.1)	208/651 (32.0)	211/651 (32.4)
ADA 40 mg EOW	16/327 (4.9)	35/327 (10.7)	43/327 (13.1)	75/327 (22.9)	74/327 (22.6)	69/327 (21.1)	75/327 (22.9)	75/327 (22.9)	68/327 (20.8)	74/327 (22.6)	68/327 (20.8)	73/327 (22.3)	71/327 (21.7)	67/327 (20.5)

Corresponding data points of categorical endpoints analyzed by randomized treatment group (NRI) shown in Figure 3 (CDAI and DAS28[CRP] responses) and Supplemental Figure 4 (ACR20/50/70 responses). ACR20/50/70, ≥20%/50%/70% improvement in American College of Rheumatology response criteria; ADA, adalimumab; EOW, every other week; NRI, non-responder imputation; QD, once daily; UPA, upadacitinib.



Supplemental Figure 1. Study Design of SELECT-COMPARE

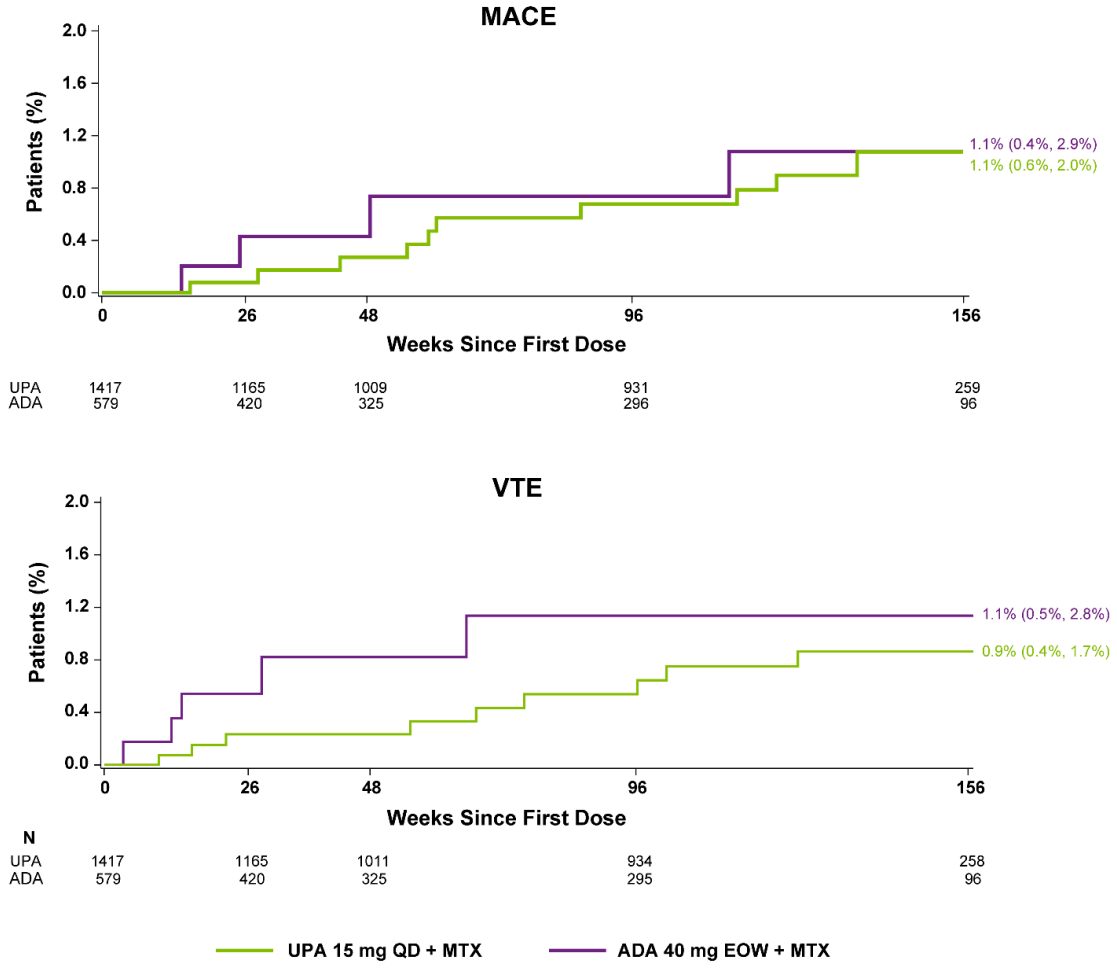
Patients continued treatment with upadacitinib or adalimumab in a blinded manner until the last patient completed the week-48 visit; patients received open-label treatment of the study drug they were assigned to thereafter. *Primary endpoints at week 12: ACR20 (FDA) DAS28-CRP <2.6 (EMA) (Fleischmann et al, 2019). †Rescue: At weeks 14, 18, and 22 if <20% improvement in TJC66 or SJC68 vs BL; at week 26, if CDAI >10. ACR20, ≥20% improvement in American College of Rheumatology response criteria; ADA, adalimumab; BL, baseline; CDAI, clinical disease activity index; CRP, C-reactive protein; DAS28(CRP), 28-joint disease activity score based on CRP; EOW, every other week; MTX, methotrexate; QD, once daily; SJC66, swollen joint count based on 66 joints; TJC68, tender joint count based on 68 joints; UPA, upadacitinib; Wk, week.



Proportion of Patients in Disease Activity States at the Visit Preceding VTE Occurrence		
	UPA + MTX (n = 9)	ADA + MTX (n = 5)
CDAI REM (≤2.8)	1 (11%)	1 (20%)
CDAI LDA (>2.8-≤10)	3 (33%)	1 (20%)
CDAI MDA (>10-≤22)	4 (44%)	0 (0%)
CDAI HDA (>22)	1 (11%)	3 (60%)
DAS28(CRP) <2.6	1 (11%)	1 (20%)
DAS28(CRP) ≥2.6-≤3.2	2 (22%)	0 (0%)
DAS28(CRP) >3.2-≤5.1	5 (56%)	3 (60%)
DAS28(CRP) >5.1	1 (11%)	1 (20%)

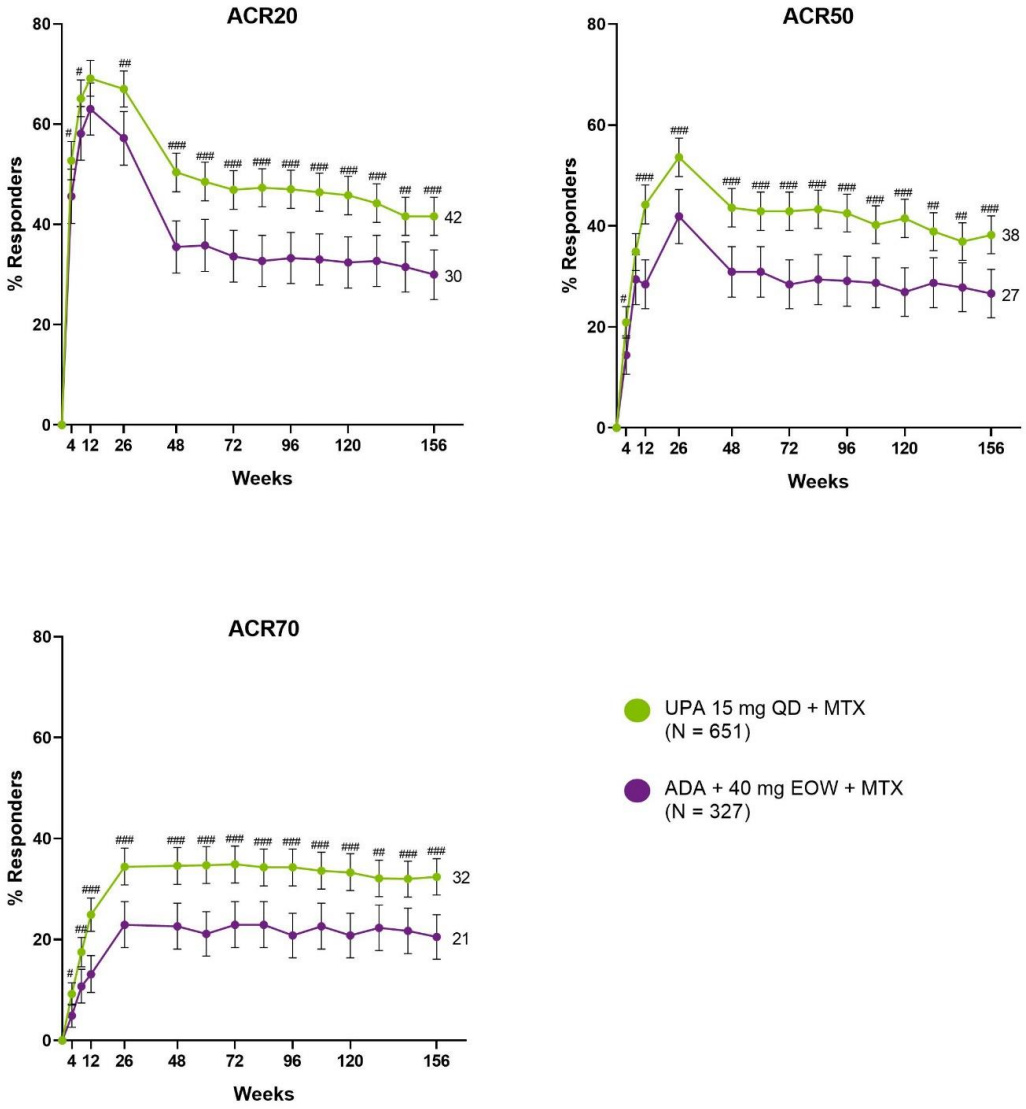
Supplementary Figure 2. Disease Activity Scores of Patients with Venous Thromboembolism Through 156 Weeks

Disease activity data through 156 weeks for all patients with venous thromboembolism events (VTEs; 9 reported on upadacitinib and 5 on adalimumab). Data include all patients receiving upadacitinib or adalimumab, including rescue groups, with assignment based on drug exposure at the time of event. Red "X" indicates occurrence of VTE. Dotted lines indicate CDAI and DAS28(CRP) disease activity thresholds. ADA, adalimumab; CDAI, clinical disease activity index; DAS28(CRP), 28-joint disease activity score based on C-reactive protein (CRP); EOW, every other week; HDA, high disease activity; MDA, moderate disease activity; MTX, methotrexate; QD, once daily; UPA, upadacitinib.



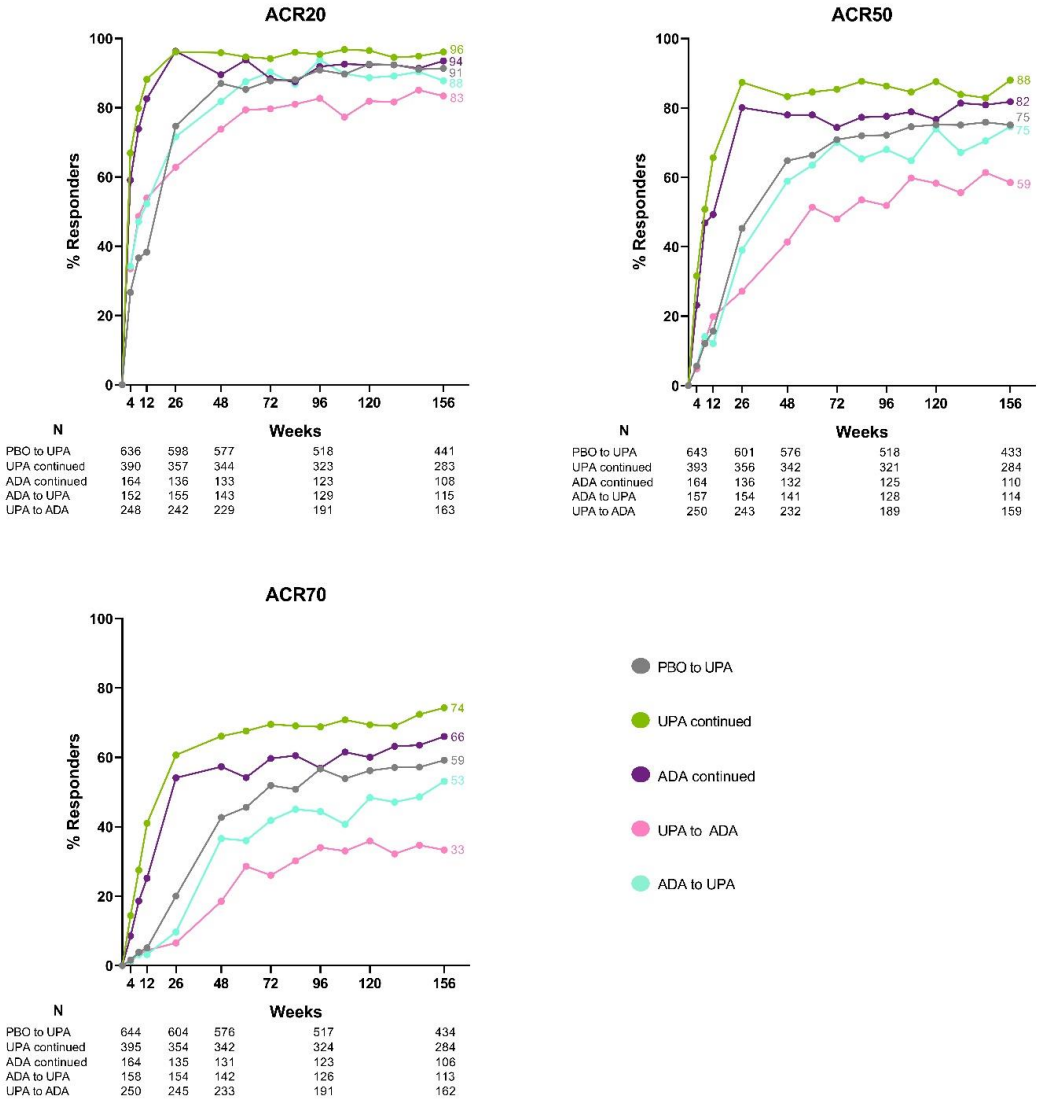
Supplemental Figure 3. Kaplan-Meier Curves of Treatment-Emergent MACE and VTE Events Through 3 Years

Data include all patients receiving upadacitinib or adalimumab, including rescue groups, with assignment based on drug exposure at the time of event. All major adverse cardiovascular events (MACE) and venous thromboembolism (VTE) events were included up to week 156. ADA, adalimumab; EOW, every other week; LDA, low disease activity; MTX, methotrexate; QD, once daily; REM, remission; UPA, upadacitinib.



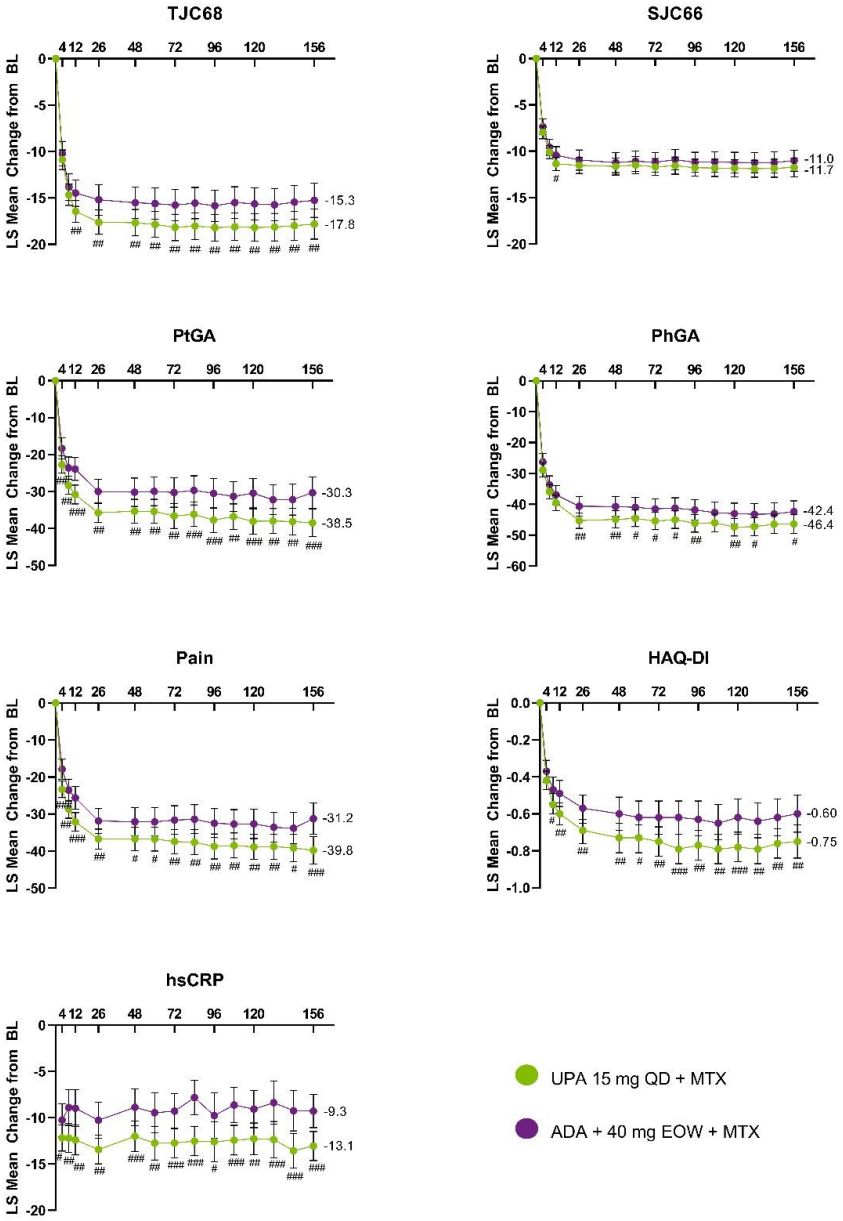
Supplemental Figure 4. Proportions of Patients Achieving ACR20, ACR50, and ACR70 Responses Through 156 Weeks (NRI)

Treatment groups are by initial randomization. #*P*<0.05, ##*P*<0.01, ###*P*<0.001 for upadacitinib vs adalimumab. All P-values are nominal. NRI was used for patients who were rescued or prematurely discontinued study drug, as well as for missing data. Data points plotted here are shown in Supplemental Table 4. ACR20/50/70, ≥20%/50%/70% improvement in American College of Rheumatology response criteria; ADA, adalimumab; EOW, every other week; MTX, methotrexate; NRI, non-responder imputation; PBO, placebo; QD, once daily; UPA, upadacitinib.



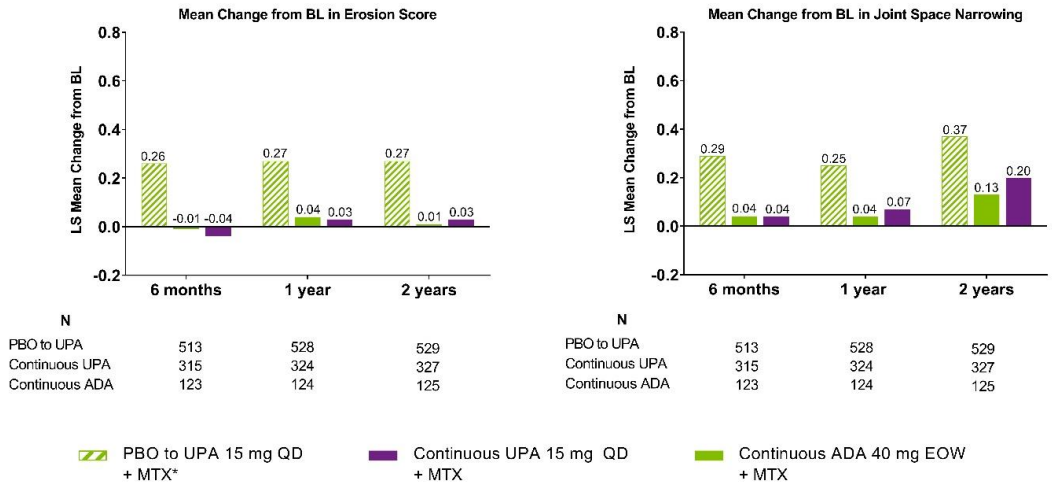
Supplemental Figure 5. Proportions of Patients Achieving ACR20, ACR50, and ACR70 Responses Through 156 Weeks (AO)

Groups are by treatment sequence as observed (AO). All patients in the placebo group who were not previously rescued were switched to upadacitinib at week 26. ACR20/50/70, ≥20%/50%/70% improvement in American College of Rheumatology response criteria; ADA, adalimumab; EOW, every other week; MTX, methotrexate; NRI, non-responder imputation; PBO, placebo; QD, once daily; UPA, upadacitinib.



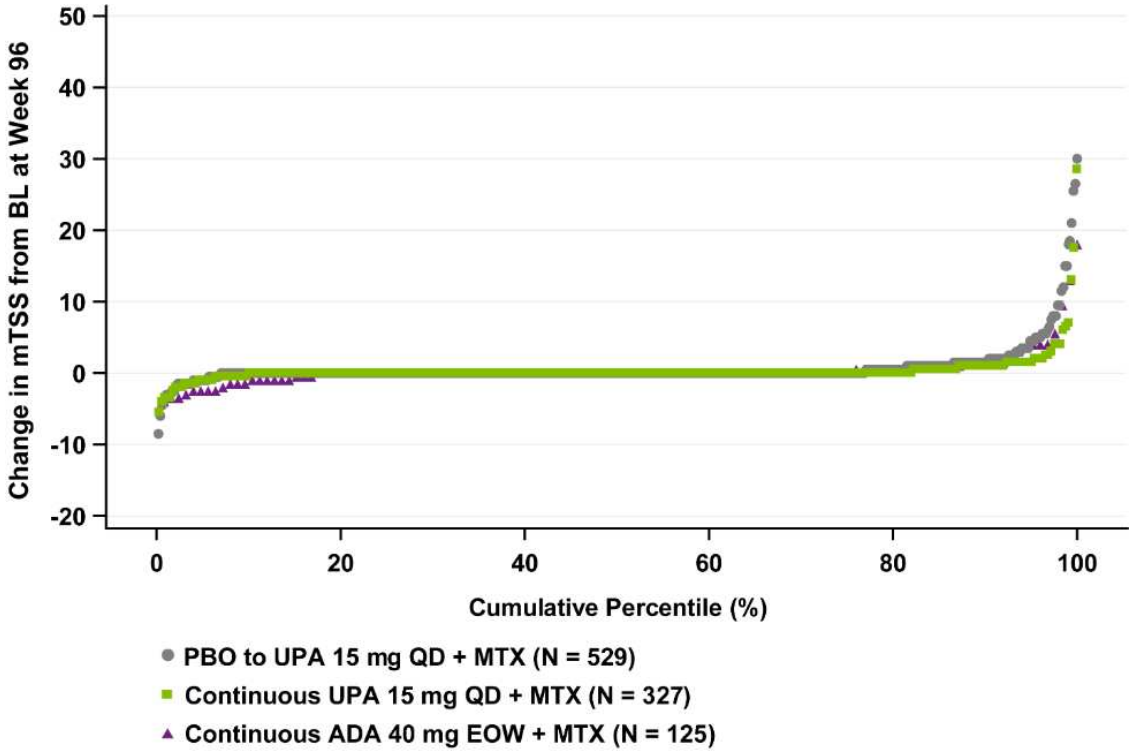
Supplemental Figure 6. Least Squares Mean Change from Baseline Over 3 Years in Core Components of the ACR Criteria (LOCF)

Treatment groups are by initial randomization. $^{\#}P<0.05$, $^{\#\#}P<0.01$, $^{\#\#\#}P<0.001$ for upadacitinib vs adalimumab. All P-values are nominal. ANCOVA with LOCF was applied for rescue treatment switch. ADA, adalimumab; ANCOVA, analysis of covariance; EOW, every other week; HAQ-DI, Health Assessment Questionnaire Disability Index; hsCRP, high-sensitivity C-reactive protein; LOCF, last observation carried forward; MTX, methotrexate; PhGA, physician's global assessment of disease activity; PtGA, patient's global assessment of disease activity; QD, once daily; SJC, swollen joint count; TJC, tender joint count; UPA, upadacitinib.



Supplemental Figure 7. Mean Change from Baseline in Erosion Score and Joint Space Narrowing (AO)

*All patients in the placebo group who were not previously rescued were switched to upadacitinib at week 26. ADA, adalimumab; BL, baseline; EOW, every other week; LS, least squares; MTX, methotrexate; PBO, placebo; QD, once daily; UPA, upadacitinib.



Supplemental Figure 8. Probability Plot of Change in mTSS from Baseline at Week 96 (AO)

*All patients in the placebo group who were not previously rescued were switched to upadacitinib at week 26. ADA, adalimumab; BL, baseline; EOW, every other week; mTSS, modified Total Sharp Score; MTX, methotrexate; QD, once daily; UPA, upadacitinib.

Opportunistic infections

Opportunistic infections (excluding tuberculosis, herpes zoster, and oral candidiasis) on upadacitinib included 4 esophageal candidiasis, 2 oral fungal infection, 1 bronchopulmonary aspergillosis, 1 fungal pharyngitis, 1 gastrointestinal candidiasis, and 1 meningitis listeria. Those reported on adalimumab included 1 esophageal candidiasis and 1 sinusitis fungal.

Herpes zoster infections

Most HZ infections were non-serious (8/87 [9%] and 0/12 [0%] of events were serious on upadacitinib and adalimumab, respectively). In addition, most HZ cases involved 1 or 2 dermatomes (53/87 [61%] and 9/12 [75%] involved only one dermatome on upadacitinib and adalimumab, respectively).

GI perforation

One treatment-emergent adjudicated GI perforation (preferred term: anal fistula) requiring surgical repair was identified in the upadacitinib-treatment group, as previously reported [10], in a 33-year-old female patient who did not have a history of GI events but who had risk factors including treatment with corticosteroids and smoking (0.15 packs per day for 3 years).

Malignancies, excluding non-melanoma skin cancer (NMSC)

Among all patients on upadacitinib, 18 malignancies (excluding NMSC) were reported. Eight occurred in the subgroup receiving continuous upadacitinib, including 2 malignant melanoma and one event each of gastric adenocarcinoma, myxoid liposarcoma, squamous cell carcinoma of the oral cavity, adenocarcinoma, glioblastoma, and breast cancer (intraductal proliferative breast lesion). Ten other malignancies occurred among patients who switched to upadacitinib: 3 lung cancer (lung carcinoma cell type unspecified Stage IV, lung adenocarcinoma, lung neoplasm malignant) and one event each of

malignant melanoma, breast cancer, colon cancer, laryngeal cancer, endometrial adenocarcinoma, metastatic squamous cell carcinoma, and malignant neoplasm of unknown primary site. Among all patients on adalimumab, 7 malignancies (excluding NMSC) were reported. Four occurred in the subgroup receiving continuous adalimumab: 1 malignant melanoma, 1 lung cancer (lung squamous cell carcinoma Stage IV), 1 B-cell lymphoma, and 1 adenocarcinoma of colon. Three malignancies occurred among patients who switched to adalimumab: 2 colon cancer and 1 large cell lung cancer.

Deaths, including non-treatment emergent deaths

Based on Cardiovascular Adjudication Committee (CAC) Decision, 4 cardiovascular (CV) deaths occurred on upadacitinib (including acute myocardial infarction, cardiac failure, and sudden death) and 2 CV deaths occurred on adalimumab (including left ventricular failure). All patients with events adjudicated as CV death had known CV risk factors in addition to their underlying RA. Twelve non-CV deaths were reported on upadacitinib, including infections (sepsis, meningitis, nosocomial infection), cancers, physical injury (such as pelvic fracture), and undetermined/unknown cause. Seven non-CV deaths were reported on adalimumab, including from infections (pneumonia), cancers, and other causes such as craniocerebral injury or undetermined/unknown cause of death.