Table 1. History of advanced therapy on or within 12 months pre-index in pts with PsA

	All pts (N=440)	Pts with no RA ^a (N=315)
Pts exposed to advanced therapy, n (%) ^b		
Any advanced therapy ^c	336 (76.4)	241 (76.5)
Secukinumab	113 (25.7)	91 (28.9)
Adalimumab	93 (21.1)	58 (18.4)
Apremilast	81 (18.4)	59 (18.7)
Etanercept	70 (15.9)	47 (14.9)
Unique advanced therapy prescriptions		
Mean (SD)	1.1 (0.8)	1.1 (0.8)
Median (IQR)	1 (1–2)	1 (1–2)
Range	0–4	0–4
Number of unique advanced therapies, n (%)		
0	104 (23.6)	74 (23.5)
1	214 (48.6)	153 (48.6)
2	100 (22.7)	73 (23.2)
≥3	22 (5.0)	15 (4.8)

^aExcludes pts with a diagnosis of RA on or within 12 months pre-index and within 6 months post-index; ^bPts with ≥1 claim for biologic DMARDs or apremilast within 12 months pre-index;

^cOther advanced therapies reported in <10% of all pts were abatacept, certolizumab, golimumab, infliximab, ixekizumab and ustekinumab (QR, interquartile range; N, number of pts per cohort; n, number of pts per category; SD, standard deviation)

Figure. Tofacitinib treatment a) persistence^a and b) adherence (PDC ≥0.8)^b in pts with PsA at 6 months post-index

^aPts with <60-day gap without tofacitinib treatment; ^bPts achieving ≥80% of days covered; ^cPts with ≥1 claim for a conventional synthetic DMARD or apremilast on or within 90 days post-index; ^dExcludes pts with a diagnosis of RA on or within 12 months pre-index and within 6 months post-index.

Figure 1

Conclusion: This analysis of US-based claims data indicated that pts newly initiated tofacitinib treatment an average of 2 years after PsA diagnosis, with the majority (>60%) of pts receiving tofacitinib as monotherapy. High levels of persistence and adherence to tofacitinib were observed 6 months after treatment initiation. Findings were similar when pts with PsA who also had a diagnosis of RA were excluded. Data were limited in that claims data cannot confirm that pts took the medication for which they filed a claim.

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AB0522

SAFETY PROFILE OF UPADACITINIB UP TO 3 YEARS IN PATIENTS WITH PSORIATIC ARTHRITIS: AN INTEGRATED ANALYSIS FROM THE PHASE 3 PROGRAM

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Background: The efficacy and safety of upadacitinib (UPA), an oral Janus kinase inhibitor, in patients (pts) with active psoriatic arthritis (PsA) were demonstrated through 24 weeks in the phase 3 SELECT-PsA 1 and SELECT-PsA 2 placebo-controlled clinical trials.^{1,2}

Objectives: To describe the long-term integrated safety profile of UPA relative to adalimumab (ADA) in pts with PsA treated in the SELECT program.

Methods: The SELECT-PsA program enrolled pts with prior inadequate response or intolerance to ≥1 non-biologic DMARD (SELECT-PsA 1) or ≥1 biologic DMARD (SELECT-PsA 2). Both trials include UPA 15 mg and 30 mg, and only SELECT-PsA 1 includes long-term comparison with ADA 40 mg every other week. Treatment-emergent adverse events (TEAEs: AE onset ≥first dose and ≤30 days after last dose for UPA and ≤70 days for ADA) were summarized for the following: pooled UPA 15; pooled UPA 30; and ADA. TEAEs are reported as exposure-adjusted event rates (EAERs; events/100 pts years [E/100 PY]) up to a cut-off date of 20 June 2020.

Results: 2257 pts received ≥1 dose of UPA 15 (N=907; 1247.2 PYs), UPA 30 (N=921; 1257.4 PYs), or ADA (N=429; 549.7 PYs), with median (max) exposures of 69 (155), 69 (154), and 68 (152) weeks, respectively. EAERs of TEAEs and serious AEs were generally similar between UPA 15 and ADA and higher with UPA 30; rates of AEs leading to study drug discontinuation were generally similar across all groups (Table 1). Similarly, rates of serious infection were comparable between UPA 15 and ADA and higher with UPA 30 (Figure 1 next page). The most common serious infection was pneumonia. Rates of herpes zoster were lower with UPA 15 than UPA 30 but higher than ADA. Most herpes zoster events involved a single dermatome; no events involved the central nervous system or other internal organs. Lower rates of opportunistic infections (OI) excluding tuberculosis were observed with UPA 15 vs UPA 30; the most common OI was mucosal candida infection. Malignancies were reported at similar rates across all treatment groups; no events of lymphoma were reported. Age-gender-adjusted standardized incidence ratios for malignancies excluding NMSC indicated no increased risk with UPA compared to the general population. Rates of adjudicated major adverse cardiovascular events and venous thromboembolic events were ≤0.3 E/100 PY for both UPA arms; all pts had ≥1 risk factor. One adjudicated gastrointestinal perforation was reported with UPA 15.

Table 1. Overall Treatment-emergent AEs for Upadacitinib and Adalimumab (E/100 PY [95% CI])

	UPA 15 mg QD N=907 (1247.2 PY)	UPA 30 mg QD N=921 (1257.4 PY)	ADA 40 mg EOW N=429 (549.7 PY)
AEs	263.9 (254.9, 272.9)	321.5 (311.6, 331.5)	286.5 (272.4, 300.7)
Serious AEs	10.3 (8.6, 12.1)	13.2 (11.2, 15.2)	9.6 (7.0, 12.2)
AE leading to discontinuation	6.7 (5.2, 8.1)	7.8 (6.2, 9.3)	7.8 (5.5, 10.2)
Deaths^a	0.2 (-0.1, 0.4)	0.2 (-0.0, 0.5)	0.2 (-0.2, 0.5)

^aDeaths included non-treatment emergent deaths: UPA 15, 1; UPA 30, 1; ADA, adalimumab; AE, adverse event; CI, confidence interval; E, event; EOW, every other week; PY, patient years; QD, once daily; UPA, upadacitinib.

Hepatic disorders were mostly transient, non-serious transaminase increases. Creatine phosphokinase elevations were reported more frequently with UPA 30 vs UPA 15; most were asymptomatic with no rhabdomyolysis reported. AEs of anemia, neutropenia, and lymphopenia were generally mild or moderate, non-serious. Except for rates of lymphopenia (higher with UPA 15), hepatic disorders, and neutropenia (both higher with ADA), lab-related TEAEs occurred at generally consistent rates between UPA 15 and ADA. Study drug discontinuation due to lab-related TEAEs was uncommon.

Conclusion: The safety profiles of UPA 15 and ADA were generally similar; the rates of most AEs were higher with UPA 30 compared with ADA. Through the cut-off date, the safety profile of UPA 15 and UPA 30 in PsA pts demonstrated consistent results compared to what has been observed with UPA in rheumatoid arthritis.³

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Figure. Exposure-adjusted Event Rates of Treatment-emergent AEs Through the Cut-off Date

*MACE was defined as CV death, non-fatal MI, and non-fatal stroke.

†Excluding tuberculosis and herpes zoster.

‡VTE was defined as deep vein thrombosis and pulmonary embolism.

ADA, adalimumab; AEs, adverse events; CI, confidence interval; CPK, creatine phosphokinase; CV, cardiovascular; E, events; EAE, exposure-adjusted event rate; EOW, every other week; GI, gastrointestinal; MACE, major adverse cardiovascular event; MI, myocardial infarction; NMSC, non-melanoma skin cancer; PY, patient year; QD, once daily; TB, tuberculosis; UPA, upadacitinib; VTE, venous thromboembolism.

Figure 1

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AB0523

LONG-TERM SAFETY AND EFFECTIVENESS OF UPADACITINIB IN PATIENTS WITH PSORIATIC ARTHRITIS: RESULTS AT 56 WEEKS FROM THE SELECT-PsA 1 STUDY

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Background: In the SELECT-PsA 1 study, through 24 weeks (wks), once daily upadacitinib 15 mg (UPA15) and 30 mg (UPA30) showed improvements in musculoskeletal symptoms, psoriasis, physical function, pain, fatigue, and quality of life, as well as inhibition of radiographic progression in patients (pts) with psoriatic arthritis (PsA) and inadequate response or intolerance to ≥ 1 non-biologic disease-modifying antirheumatic drug (DMARD).¹

Objectives: To report the efficacy and safety of UPA vs adalimumab (ADA) up to 56 wks from the ongoing long-term extension of SELECT-PsA 1.

Methods: Pts received UPA15 or UPA30, ADA 40mg every other wk for 56 wks, or PBO through wk 24 switched thereafter to either UPA15 or UPA30 until wk 56. Efficacy endpoints as listed and defined in the Table 1 were analyzed at wk 56. Results for binary endpoints are based on non-responder imputation analysis; treatments were compared using the Cochran-Mantel-Haenszel test. Results for non-radiographic continuous endpoints are based on mixed model repeated measures model based on as observed data. Radiographic endpoints were analyzed based on linear extrapolation. Treatment-emergent adverse events (TEAEs) per 100 pt years (PY) were summarized for pts who received ≥ 1 dose of study drug.

Table 1. Efficacy Endpoints at Week 56

Endpoint	PBO → UPA15	PBO → UPA30	UPA15	UPA30	ADA
ACR20, %	73.0	74.1	74.4	74.7 [#]	68.5
ACR50, %	54.5	60.4	59.7 [*]	60.5 [#]	51.3
ACR70, %	29.9	35.8	40.6 [*]	43.7 [#]	31.2
Minimal Disease Activity, %	29.4	35.8	44.8	47.3 [#]	39.6
PASI75 ^a , %	58.3	60.2	65.4	63.3	61.1
PASI90 ^a , %	41.7	53.7	49.1	49.5	46.9
PASI100 ^a , %	22.3	38.9	34.6	39.5	31.3
Resolution of enthesitis by Leeds Enthesitis Index ^b , %	38.1	45.5	59.3	58.1	54.0
Resolution of dactylitis by Leeds Dactylitis Index ^c , %	47.7	59.0	75.0	74.8	74.0
Δ from BL in Bath Ankylosing Spondylitis Disease Activity Index ^d	-3.1	-3.1	-3.3	-3.2	-2.8
Δ from BL in modified total Sharp/van der Heijde Score (mTSS)	0.44 ^e	-0.05 [†]	0.02 [‡]	-0.06	

* and †, p $\leq$ 0.05; for UPA15 vs ADA and PBO, respectively; # and ‡, p $\leq$ 0.05; for UPA30 vs ADA and PBO, respectively. ^a for pts with psoriasis affecting $\geq 3\%$ of body surface area at BL. ^b for pts with LEI >0 at BL. ^c for pts with LDI >0 at BL. ^d for pts with psoriatic spondylitis at BL. ^e pooled PBO.ACR20/50/70, $\geq 20\%/50\%/70\%$ improvement in American College of Rheumatology criteria; ADA, adalimumab; BL, baseline; PASI75/90/100, $\geq 75\%/90\%/100\%$ improvement in Psoriasis Area and Severity Index; PBO, placebo; pts, patients; UPA, upadacitinib.

Results: Of 1704 pts who received ≥ 1 dose of study drug, 1419 (83.2%) completed 56 wks of treatment on study drug. Across all treatment groups, the proportions of pts who had achieved ACR20/50/70, MDA, PASI75/90/100, resolution