12 months; NCT01877668]), or had an IR to ≥ 1 TNFi (OPAL Beyond [n=394; 6 months; NCT01882439]). Pts were randomised to receive tofacitinib 5 mg twice daily (BID), tofacitinib 10 mg BID, adalimumab 40 mg subcutaneous injection once every 2 weeks (OPAL Broaden only) or PBO (advancing to tofacitinib 5 or 10 mg BID at Month 3, OPAL Broaden and OPAL Beyond), in addition to continuing on a single, stable csDMARD. Composite endpoints assessed: Psoriatic Arthritis Disease Activity Score (PASDAS), Disease Activity Score using 28 joints with C-reactive protein, Disease Activity Index for Reactive Arthritis/Psoriatic Arthritis (DAREA/DAPSA) and Composite Psoriatic Disease Activity Index (CPDAI).

Results: Demographics and baseline disease characteristics were generally similar between treatment groups within the 2 studies, except for duration of PsA disease (longer in OPAL Beyond) and geographic distribution (OPAL Broaden having more Eastern EU pts). Baseline values for composite endpoints were generally similar across treatment groups and studies (table 1). Both doses of tofacitinib showed improvements in composite endpoints vs PBO at Month 3 in both studies (table 1). In OPAL Broaden, the effects of adalimumab were similar to both doses of tofacitinib across composite endpoints. Effect size for the composite endpoints (using a subpopulation of pts who had all available data for all endpoints) was highest for PASDAS and typically lowest for DAREA/DAPSA; this rank order of effect size was similar across treatment arms and studies. At Month 3, effect sizes in pts receiving active treatment ranged from 0.90 (DAREA/DAPSA for tofacitinib 5 mg BID) to 2.40 (PASDAS for tofacitinib 10 mg BID) in OPAL Broaden, and 0.81 (DAREA/DAPSA for tofacitinib 5 mg BID) to 1.84 (PASDAS for tofacitinib 10 mg BID) in OPAL Beyond (table 1). Standardised response means generally followed the same pattern as effect size across studies with both doses of tofacitinib (table 1).

Abstract THU0323 – Table 1. Summary of mean at baseline, LS mean change from baseline, effect size and standardised response mean at Month 3 for composite endpoints (PASDAS, DAS28-3(CRP), DAREA/DAPSA, CPDAI) in OPAL Broaden and OPAL Beyond studies

	OPAL Broaden				OPAL Beyond			
	Tofacitinib 5 mg BID N=107	Tofacitinib 10 mg BID N=104	Adalimumab 40 mg SC Q2W N=106	Placebo N=105	Tofacitinib 5 mg BID N=121	Tofacitinib 10 mg BID N=122	Placebo N=131	
Baseline means (SD) [N]								
PASDAS	6.03 (1.15) [105]	6.01 (1.06) [102]	5.92 (1.25) [106]	6.03 (1.15) [103]	5.09 (1.22) [124]	6.43 (1.21) [128]	5.97 (1.26) [128]	
DAS28-3(CRP)	4.56 (0.92) [107]	4.48 (0.87) [104]	4.38 (1.02) [106]	4.50 (1.04) [105]	4.51 (0.94) [131]	4.67 (1.17) [132]	4.40 (1.03) [131]	
DAREA/DAPSA	45.55 (20.33) [107]	43.89 (19.31) [104]	38.52 (18.17) [105]	43.81 (22.46) [105]	45.53 (23.51) [130]	51.54 (27.80) [132]	42.64 (22.99) [131]	
CPDAI*	9.9 (2.39) [81]	10.0 (2.36) [84]	9.7 (2.46) [77]	9.9 (2.65) [81]	10.1 (2.58) [79]	10.7 (2.56) [79]	9.6 (2.86) [83]	
LS mean change from baseline at Month 3 (SE) [N]†								
PASDAS	-1.99*** (0.14) [104]	-2.30*** (0.14) [102]	-2.17*** (0.14) [106]	-1.21 (0.15) [101]	-1.93*** (0.14) [121]	-2.14*** (0.14) [124]	-0.83 (0.14) [126]	
DAS28-3(CRP)	-1.33*** (0.10) [107]	-1.63*** (0.10) [104]	-1.51*** (0.10) [106]	-0.77 (0.11) [101]	-1.38*** (0.10) [130]	-1.23*** (0.10) [132]	-0.61 (0.10) [131]	
DAREA/DAPSA	-26.30*** (1.72) [107]	-24.49*** (1.73) [104]	-19.30*** (1.73) [105]	-13.79 (1.82) [101]	-22.46*** (1.67) [129]	-21.04*** (1.70) [132]	-6.60 (1.69) [131]	
CPDAI*	-2.9 (0.34) [81]	-4.2*** (0.36) [84]	-3.1* (0.34) [77]	-2.2 (0.36) [80]	-3.3*** (0.31) [78]	-3.4*** (0.31) [78]	-1.6 (0.31) [83]	
Effect size at Month 3								
	N3=68	N3=62	N3=66	N3=77	N3=64	N3=62	N3=72	
PASDAS	1.73	2.40	1.60	1.01	1.53	1.84	0.74	
DAS28-3(CRP)	1.47	1.77	1.37	0.73	1.07	1.16	0.63	
DAREA/DAPSA	0.90	1.25	1.05	0.36	0.81	0.84	0.51	
CPDAI	1.03	1.43	1.05	0.60	1.41	1.45	0.50	
Standardised response mean at Month 3								
PASDAS	1.42	1.75	1.73	1.19	1.26	1.53	0.65	
DAS28-3(CRP)	1.25	1.46	1.50	0.79	1.14	1.29	0.61	
DAREA/DAPSA	1.05	1.25	1.47	0.78	0.94	1.15	0.38	
CPDAI	0.89	1.27	1.11	0.80	1.11	1.49	0.63	

Nominal *p<0.05; **p<0.01; ***p<0.001 vs placebo at baseline

*For CPDAI, only patients with BL ESA ≥3% were included

†Based on MMRM model including data from baseline up to Month 3 without imputation

N = Number of patients in the FAS

N1 = Number of patients evaluable at baseline

N2 = Number of patients included in the MMRM model

N3 = Number of patients with BL ESA ≥3% in the FAS and with non-missing values of all 4 composite endpoints across visits of baseline, Month 3 (baseline and Month 3 only for placebo groups), Month 6 and Month 12 (for OPAL Broaden only). This subpopulation was used for the calculation of effect sizes and standardised response means across visits

Effect size at Month 3 was defined as (mean at baseline – mean at Month 3)/SD at baseline; standardised response mean at Month 3 was defined as (mean at baseline – mean at Month 3)/SD of change from baseline at Month 3
BID, twice daily; BL, baseline; BSA, body surface area; CPDAI, Composite Psoriatic Disease Activity Index; CRP, C-reactive protein; DAREA/DAPSA, Disease Activity Index for Reactive Arthritis/Psoriatic Arthritis; DAS28-3, Disease Activity Score using 28 joints; FAS, full analysis set; LS, least squares; MMRM, mixed model for repeated measures; PASDAS, Psoriatic Arthritis Disease Activity Score; Q2W, every 2 weeks; SC, subcutaneous; SD, standard deviation; SE, standard error of LS mean

Conclusions: In 2 Phase 3 studies, tofacitinib 5 mg and 10 mg BID improved composite endpoint scores vs PBO over 3 months in pts with PsA. The largest effect size and standardised response means were observed for PASDAS. Effect sizes and standardised response means varied across endpoints but were consistent across studies.

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THU0324 DISEASE ACTIVITY AND PATIENT CHARACTERISTICS BY COMORBIDITY AMONG PSORIATIC ARTHRITIS (PSA) PATIENTS IN A US REGISTRY

¹P.J. Mease, H.J. Litman², N.A. Accortt³, S. Rebello⁴, J.D. Greenberg⁴, H. Feng², M.M. Gharaibeh³, G.A. Aras³, D.H. Collier³. ¹Swedish Medical Center and University of Washington, Seattle WA; ²Corona LLC, Waltham MA; ³Amgen Inc., Thousand Oaks CA; ⁴New York University, New York NY, USA

Background: PsA patients have greater prevalence of cardiovascular disease (CVD), metabolic syndrome (MetS), and cancer than patients without PsA.

Objectives: To examine patient characteristics and disease activity by comorbidity profile among PsA patients.

Methods: This analysis included adults with PsA enrolled in the US Corona PsA/spondyloarthritis Registry from March 2013-March 2017 and followed for ≥ 6 months. Prevalence (at registry entry) and incidence rate (time to new events after registry entry) of CVD, MetS, and cancer were determined. Patient characteristics and disease activity were described by prevalent comorbidity, with t-tests for means despite skewed data and chi-squared tests for percentages.

Results: The analysis included 1493 patients and 3564 patient-years of follow-up. Incidences (95% confidence interval) per 1000 patient-years were 9.4 (6.5–13.5), 1.0 (0.3–3.1), and 11.4 (8.2–15.8) for CVD, MetS, and cancer (6.8 [4.5–10.2] nonmelanoma skin cancer), respectively. PsA patients with (vs without) prevalent CVD, MetS, or cancer were older, and fewer had full-time jobs or private insurance. Patients with (vs without) CVD had higher swollen joint count and mean body surface area, and tended to have higher rates of obesity. Patients with (vs without) MetS tended to have greater disease activity. Patients with (vs without) comorbidities reported less disease activity on patient global assessment. Data are mean or %

≥ 3 of 4 conditions: hypertension, hyperlipidemia, diabetes mellitus, or obesity

^bP value across all categories for employment or body mass index

Conclusions: PsA patients with (vs without) CVD had greater disease activity and those with (vs without) MetS tended to have greater disease activity by physician-derived measures, but PsA patients with (vs without) CVD or MetS reported lower global assessment of disease activity. Patient perception of PsA may mask the effect of comorbid CVD or MetS on disease activity.

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