may pioneer further studies investigating the usage of adipokines such as vaspin and lipocalin2 levels as biomarkers in the diagnose and disease course of PsA.

Disclosure of Interest: None declared

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AB0902

EFFICACY OF TOFACITINIB BY BACKGROUND METHOTREXATE DOSE IN PATIENTS WITH PSORIATIC ARTHRITIS: A POST-HOC ANALYSIS OF POOLED DATA FROM 2 PHASE 3 TRIALS

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Background: Tofacitinib is an oral Janus kinase inhibitor for the treatment of psoriatic arthritis (PsA). The efficacy of tofacitinib has been evaluated in 2 Phase 3 studies in patients (pts) with PsA.

Objectives: To describe the efficacy of tofacitinib by background methotrexate (MTX) dose in pts with PsA.

Methods: This post-hoc analysis utilised efficacy data pooled from 2 Phase 3, randomised, double-blind, placebo-controlled studies (OPAL Broaden [12 months; NCT01877668] and OPAL Beyond [6 months; NCT01882439]) in pts with a diagnosis (≥ 6 months) of active PsA (≥ 3 swollen and ≥ 3 tender joints). Pts in OPAL Broaden were tumour necrosis factor inhibitor (TNFi)-naïve and had an inadequate response (IR) to ≥ 1 conventional synthetic disease-modifying antirheumatic drug (csDMARD). Pts in OPAL Beyond had an IR to ≥ 1 TNFi. Pts were randomised to tofacitinib 5 or 10 mg twice daily (BID), placebo or adalimumab 40 mg subcutaneous every 2 weeks (OPAL Broaden; adalimumab data not shown). All pts received a stable dose of 1 csDMARD (eg MTX, leflunomide or sulfasalazine) as background therapy. The maximum dose of MTX allowed per protocol was 20 mg/week. Efficacy outcomes for tofacitinib at Month 3 were evaluated by background MTX dose (≤ 15 vs > 15 mg/week) and included: ACR20/50/70 response rates ($\geq 20/50/70\%$ improvement from baseline, respectively), Health Assessment Questionnaire-Disability Index (HAQ-DI) response rate (reduction from baseline ≥ 0.35 points) and mean change from baseline in HAQ-DI score. Analyses were based on the full analysis set for pts receiving MTX on Day 1; pts with missing data were considered as having a non-response for binary endpoints. No statistical testing was performed.

Results: In total, data from 556 pts who received tofacitinib plus MTX only or placebo plus MTX only (tofacitinib 5 mg BID, n=186; tofacitinib 10 mg BID, n=178; placebo, n=192) were included in this analysis. Most pts were treated with background MTX at doses ≤ 15 mg/week (n=371, 66.7%; mean [SD] dose, 12.6 [3.1] mg/week) vs > 15 mg/week (n=185, 33.3%; mean [SD] dose, 19.8 [0.8] mg/week). Baseline demographics and disease characteristics were generally similar between arms in MTX dose groups (table 1). At Month 3, tofacitinib 5 and 10 mg BID were generally associated with numerically greater ACR and HAQ-DI response rates and greater changes from baseline in HAQ-DI score compared with placebo. The magnitude of tofacitinib effects on efficacy outcomes appeared broadly similar between background MTX dose groups (table 1).

Abstract AB0902 – Table 1. Patient demographics and disease characteristics at baseline, and efficacy outcomes at Month 3 by MTX dose

	MTX dose ≤ 15 mg/week			MTX dose > 15 mg/week		
	Tofacitinib 5 mg BID (N=186)	Tofacitinib 10 mg BID (N=178)	Placebo (N=192)	Tofacitinib 5 mg BID (N=186)	Tofacitinib 10 mg BID (N=178)	Placebo (N=192)
Patient demographics and disease characteristics						
Female, n (%)	50 (26.9)	71 (39.9)	71 (37.0)	43 (23.1)	31 (17.4)	32 (16.7)
Age, mean (SD), years	49.9 (12.6)	48.7 (10.4)	49.8 (12.4)	49.8 (13.8)	47.4 (12.2)	48.9 (12.7)
Disease duration, mean (SD), years	8.4 (7.8)	7.8 (8.3)	8.6 (8.3)	9.3 (8.7)	7.4 (8.9)	8.7 (8.1)
Duration of swollen joints, mean (SD), joints	9.5 (9.4)	9.5 (9.4)	9.5 (9.4)	9.5 (9.4)	9.5 (9.4)	9.5 (9.4)
Duration of tender joints, mean (SD), joints	18.0 (14.0)	18.1 (14.0)	17.9 (14.0)	18.0 (14.0)	18.0 (14.0)	18.0 (14.0)
HAQ-DI, mean (SD)	1.1 (0.7)	1.2 (0.6)	1.2 (0.7)	1.2 (0.6)	1.3 (0.6)	1.2 (0.6)
CRP, mean (SD), mg/L	12.3 (21.5)	10.3 (20.1)	9.7 (21.1)	11.9 (20.0)	13.4 (22.4)	14.1 (23.6)
MTX dose, mean (SD), mg/week	12.6 (3.1)	12.6 (3.1)	12.6 (3.1)	19.8 (0.8)	19.8 (0.8)	19.8 (0.8)
HAQ-DI, mean (SD)	1.1 (0.7)	1.2 (0.6)	1.2 (0.7)	1.2 (0.6)	1.3 (0.6)	1.2 (0.6)
Efficacy outcomes at Month 3						
ACR20 response rate, % (95% CI)	47.4 (45.5-49.3)	54.9 (51.3-58.5)	34.3 (31.3-37.3)	51.4 (46.7-56.1)	51.8 (46.5-57.1)	38.3 (34.5-42.1)
ACR50 response rate, % (95% CI)	27.8 (25.1-30.5)	39.3 (34.2-44.4)	21.3 (17.3-25.3)	35.7 (29.7-41.7)	35.6 (29.6-41.6)	23.3 (18.3-28.3)
ACR70 response rate, % (95% CI)	12.8 (9.1-16.5)	19.7 (14.7-24.7)	6.3 (3.3-9.3)	24.3 (17.0-31.6)	24.3 (17.0-31.6)	10.3 (6.3-14.3)
HAQ-DI response rate (score ≥ 0.35), % (95% CI)	47.4 (46.1-48.7)	52.8 (48.8-56.8)	34.3 (31.3-37.3)	51.7 (46.9-56.5)	51.4 (46.1-56.7)	35.8 (31.8-39.8)
HAQ-DI, mean change from baseline (95% CI)	-0.31 (0.40)	-0.40 (0.36)	-0.37 (0.40)	-0.39 (0.46)	-0.39 (0.46)	-0.38 (0.46)

*Among pts with baseline HAQ-DI score ≥ 0.35

Missing values for ACR20/50/70 response rates and HAQ-DI response rate were considered as non-response to treatment

LSM were calculated based on a mixed model for repeated measures without imputation for missing values

The maximum permitted dose of MTX was 20 mg/week

The analyses included all pts who received MTX as background therapy only on Day 1 in the FAS

ACR, American College of Rheumatology; BID, twice daily; CRP, C-reactive protein; FAS, full analysis set; HAQ-DI, Health Assessment Questionnaire-Disability Index; LSM, least squares mean; MTX, methotrexate; n, number of pts with response; N, number of pts included in the analysis; N1, number of pts included in the HAQ-DI response analysis; N2, number of pts evaluable for change from baseline in HAQ-DI at Month 3; pts, patients; SD, standard deviation; SE, standard error

Conclusions: The results of this pooled analysis suggest that the efficacy of tofacitinib in pts with PsA was greater than placebo and does not differ when evaluated by background MTX dose (≤ 15 vs > 15 mg/week), although small pt numbers in some groups may limit the conclusions that can be made. These results are consistent with findings from similar analyses of tofacitinib in pts with rheumatoid arthritis.

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AB0903

EFFICACY OF TILDRAKIZUMAB IN ETANERCEPT PARTIAL OR NONRESPONDERS

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Background: Etanercept (ETN) is an anti-tumour necrosis factor (TNF) medication that was among the first biologics approved for psoriasis. Additional medications have been developed or are in development for psoriasis, and patients who do not adequately respond to ETN may benefit from these more recent biologics.

Objectives: Here we report the efficacy of tildrakizumab (TIL), a humanised anti-IL-23p19 monoclonal antibody, as evaluated in patients with moderate to severe chronic plaque psoriasis who were partial (Psoriasis Area and Severity Index [PASI] ≥ 50 – < 75) or nonresponders (PASI < 50) to ETN and subsequently rerandomized to TIL in the phase 3 reSURFACE 2 trial (NCT01729754).

Methods: Patients with psoriasis ($\geq 10\%$ body surface area, Physician's Global Assessment [PGA], and PASI ≥ 12) participated in reSURFACE 2, a 3-part, 52 week, randomised controlled trial. In Part 1 (Weeks 0–12), patients were randomised to subcutaneous TIL 200 mg, TIL 100 mg, or placebo (PBO) administered at Weeks 0 and 4, or ETN 50 mg administered twice weekly. In Part 2 (Weeks 12–28), TIL and ETN patients remained on the same treatment (TIL administered at Week 16; ETN once weekly), whereas PBO patients were rerandomized to TIL 100 or 200 mg. In Part 3 (Weeks 28–52), ETN responders (PASI ≥ 75) were discontinued, and partial and nonresponders were switched to TIL 200 mg (administered at Weeks 32, 36, and 48). For this post hoc analysis, the proportion of patients ($\pm$ SD) with PASI response and PGA response (score of 0 [clear] or 1 [minimal]) with at least a 2-grade score reduction from baseline were determined at Week 52. Primary results from the trial have been previously reported.¹

Results: In total, 1090 patients were randomised. Of the 313 patients randomised to ETN, by Week 28 there were 83 partial responders and 39 nonresponders. At Week 52 (after 20 weeks of TIL treatment) for ETN partial responders, 75% $\pm$ 5%, 34% $\pm$ 5%, 15% $\pm$ 4%, and 58% $\pm$ 5% had achieved PASI 75, 90, 100, and PGA response of 0/1, respectively, with TIL 200 mg treatment. At Week 52 for ETN nonresponders, 54% $\pm$ 6%, 31% $\pm$ 5%, 10% $\pm$ 3%, and 56% $\pm$ 5% had achieved PASI 75, 90, 100, and PGA response of 0/1, respectively, with TIL 200 mg treatment. Adverse events were similar in patients switched from ETN to TIL at Week 28, compared with the patients who were maintained on TIL through Week 52.

Conclusions: A substantial portion of patients with moderate to severe chronic plaque psoriasis who were partial or nonresponders to ETN may respond after switching to treatment with TIL 200 mg. TIL may be a reasonable option for those who do not achieve adequate response to ETN.

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AB0904 CORRELATION OF RAPID3 AND PROMIS10 IN PATIENTS WITH PSORIATIC ARTHRITIS

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Background: In addition to clinician assessment and laboratory tests, patient-reported outcomes (PROs) are important for managing and improving the quality of care in patients with psoriatic arthritis (PsA). The RAPID3 was originally developed for use in patients with rheumatoid arthritis, but it may be used in clinical practice to assess disease activity in patients with PsA.¹ The PROMIS10 is a general (nondisease-specific) PRO instrument that measures physical, mental, and social health.² Developed for the general population, PROMIS10 has not yet been specifically validated in PsA.

Objectives: To evaluate the relationship between RAPID3 and PROMIS10 in patients with PsA.

Methods: US adults with a self-reported diagnosis of PsA were recruited through CreakyJoints (www.CreakyJoints.org), an online patient support community comprising patients with arthritis and arthritis-related diseases and their caregivers. Respondents completed an online survey that was designed to collect data on socio-demographics and clinical symptoms and included the RAPID3 and PROMIS10 to evaluate disease activity and health-related quality of life (HRQoL), respectively. The RAPID3 consists of three patient self-reported scores (0–10): functional impairment, pain, and patient global assessment; total score ≤ 3.0 = near remission, 3.1 to 6.0 = low disease severity, 6.1 to 12.0 = moderate disease severity, and ≥ 12.1 = high disease severity. PROMIS10 is a 10-item survey measuring physical and mental domains; individual scores are transformed to T-score distributions normalised to the general population. PROMIS10 individual scores and global physical and mental health T-scores were stratified by RAPID3 disease severity and compared across RAPID3 severity levels using Kruskal-Wallis or ANOVA tests, respectively. Spearman's correlation coefficient was calculated between RAPID3 total score and the PROMIS10 physical health and mental health T-scores, respectively.

Results: Among 203 respondents, the mean (SD) age was 51.6 (10.8) years and 172 (84.7%) were female. The mean (SD) cumulative RAPID3 score was 14.7 (5.8) with mean (SD) functional impairment, pain tolerance, and patient's global estimate scores of 3.3 (1.8), 6.0 (2.3), and 5.4 (2.5), respectively. Patients' mean (SD) PROMIS10 global physical and mental health T-scores were 36.4 (7.3) and

40.2 (9.3), respectively. The mean individual domain scores and global T-scores worsened with increasing RAPID3 disease severity levels (all $p < 0.001$) (table 1). PROMIS10 physical and mental health T-scores showed a strong ($r_s = -0.84$) and moderate correlation ($r_s = -0.57$) with RAPID3, respectively.

Abstract AB0904 – Table 1. PROMIS10 Scores and Impact of PsA on Work by RAPID3 Disease Activity in Patients with PsA

	RAPID3 Disease Activity*				P value
	Near Remission	Low Severity	Moderate Severity	High Severity	
PROMIS10 domain, mean (SD)	n = 5	n = 14	n = 45	n = 139	
Overall health	3.60 (0.55)	2.93 (0.73)	2.87 (0.69)	2.10 (0.73)	< 0.0001
Quality-of-life	4.20 (0.84)	3.07 (0.83)	3.16 (0.74)	2.29 (0.89)	< 0.0001
Physical health	3.60 (0.55)	2.79 (0.89)	2.73 (0.62)	1.97 (0.73)	< 0.0001
Mental health	4.40 (0.55)	3.14 (1.10)	3.11 (1.05)	2.63 (1.10)	0.0004
Satisfaction with social activities/relationships	4.20 (0.45)	3.00 (0.96)	3.09 (1.06)	2.06 (1.09)	< 0.0001
Ability to carry out every day physical activities	4.80 (0.45)	4.36 (0.63)	3.80 (0.73)	2.68 (0.76)	< 0.0001
Emotional distress	4.80 (0.45)	3.43 (1.16)	3.16 (0.80)	2.65 (1.00)	< 0.0001
Fatigue	4.00 (1.00)	3.50 (0.65)	3.04 (0.71)	2.25 (0.76)	< 0.0001
Pain	4.20 (0.45)	3.93 (0.27)	3.38 (0.49)	2.40 (0.56)	< 0.0001
Global physical health T-score	52.84 (3.07)	46.66 (3.69)	42.35 (4.54)	32.91 (5.06)	< 0.0001
Global mental health T-score	58.44 (5.86)	45.17 (7.60)	44.84 (7.53)	37.50 (8.56)	< 0.0001

PROMIS10, Patient-Reported Outcome Management Information System Global Health short form; RAPID3, Routine Assessment of Patient Index Data 3.

* Disease severity classified by RAPID3 scores: ≤ 3.0 = near remission; 3.1 to 6.0 = low severity; 6.1 to 12.0 = moderate severity; ≥ 12.1 = high severity.

Conclusions: RAPID3 and PROMIS10 physical health T-scores were strongly correlated in patients with PsA. PROMIS10 mental health scores moderately correlated with RAPID3, suggesting the mental health questions add a different construct. PROMIS10 and RAPID3 are relatively short questionnaires that can be used in the real world to track and monitor disease symptoms and HRQoL in patients with PsA.

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AB0905 LONG-TERM (5-YEAR) EFFICACY AND SAFETY OF APREMILAST MONOTHERAPY IN DMARD-NAÏVE SUBJECTS WITH ACTIVE PSORIATIC ARTHRITIS

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Background: Apremilast (APR) is an oral phosphodiesterase 4 inhibitor that helps regulate the immune responses that cause joint inflammation and other manifestations of psoriatic arthritis (PsA), including skin disease.