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

DOI: 10.1136/annrheumdis-2018-eular.7237

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

A.J. Kivitz¹, O. FitzGerald², P. Nash³, S. Pang⁴, V.F. Azevedo⁵, E. Kudlacz⁶, C. Wang⁶, D. Graham⁶, L. Takiya⁷. ¹Department of Rheumatology, Altoona Center for Clinical Research, Duncansville, PA, USA; ²Department of Rheumatology, St Vincent's University Hospital, Dublin, Ireland; ³Department of Medicine, University of Queensland, St Lucia, Brisbane, Australia; ⁴St. Jude Medical Center, Fullerton, CA, USA; ⁵Universidade Federal do Paraná, Curitiba, Brazil; ⁶Pfizer Inc, Groton, CT; ⁷Pfizer Inc, Collegeville, PA, USA

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)	48.8 (12.4)	49.8 (13.8)	47.4 (12.2)	46.9 (12.7)
Disease duration, mean (SD), years	8.4 (7.8)	7.8 (6.3)	8.6 (8.3)	9.3 (8.7)	7.4 (6.9)	6.7 (5.1)
Number of swollen joints, mean (SD)	9.5 (3-40)	9.5 (3-40)	9.5 (3-40)	9.5 (3-40)	9.5 (3-40)	7.0 (3-32)
Number of tender joints, mean (SD)	18.0 (4-60)	18.1 (4-60)	17.0 (4-60)	18.9 (4-60)	18.9 (4-60)	13.0 (4-60)
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 response rate (score ≥ 0.35)	47.4 (25.5)	54.9 (28.0)	34.3 (17.9)	51.4 (26.7)	51.8 (26.5)	38.0 (19.5)
ACR20 response rate, % (n/N)	27.8 (20/72)	39.3 (28/72)	11.3 (8/72)	35.7 (25/70)	35.6 (24/67)	13.3 (9/67)
ACR50 response rate, % (n/N)	12.4 (9/72)	19.7 (14/72)	4.3 (3/72)	24.3 (17/70)	24.3 (17/70)	8.8 (6/67)
HAQ-DI response rate (score ≥ 0.35)	47.4 (25.5)	54.9 (28.0)	34.3 (17.9)	51.4 (26.7)	51.8 (26.5)	38.0 (19.5)
HAQ-DI LSM (95% CI)	-0.31 (0.40)	-0.40 (0.36)	-0.17 (0.34)	-0.39 (0.46)	-0.26 (0.37)	-0.18 (0.34)

*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.

Acknowledgements: Study sponsored by Pfizer Inc. Medical writing support was provided by C Viegelmann of CMC and funded by Pfizer Inc.

Disclosure of Interest: A. Kivitz Consultant for: AbbVie, Celgene, Genentech, Genzyme, Janssen, Merck, Novartis, Pfizer Inc, Sanofi and UCB, Speakers bureau: AbbVie, Celgene, Genentech, Genzyme, Janssen, Merck, Novartis, Pfizer Inc, Sanofi and UCB, O. FitzGerald Grant/research support from: AbbVie, BMS, Novartis, Pfizer Inc, Consultant for: Amgen, Celgene, Eli Lilly, Janssen, P. Nash Grant/research support from: AbbVie, BMS, Eli Lilly, Janssen, Novartis, Pfizer Inc, Roche, Sanofi, UCB, Consultant for: AbbVie, BMS, Eli Lilly, Janssen, Novartis, Pfizer Inc, Roche, Sanofi, UCB, Speakers bureau: AbbVie, BMS, Eli Lilly, Janssen, Novartis, Pfizer Inc, Roche, Sanofi, UCB, S. Pang: None declared, V. Azevedo Grant/research support from: AbbVie, Eli Lilly, Genentech, GSK, Pfizer Inc, UCB, Consultant for: AbbVie, Merck-Serono, Novartis, Pfizer Inc, Speakers bureau: AbbVie, Janssen, Merck-Serono, Novartis, Pfizer Inc, Sanofi, E. Kudlacz Shareholder of: Pfizer Inc, Employee of: Pfizer Inc, C. Wang Shareholder of: Pfizer Inc, Employee of: Pfizer Inc, D. Graham Shareholder of: Pfizer Inc, Employee of: Pfizer Inc, L. Takiya Shareholder of: Pfizer Inc, Employee of: Pfizer Inc

DOI: 10.1136/annrheumdis-2018-eular.1278

AB0903

EFFICACY OF TILDRAKIZUMAB IN ETANERCEPT PARTIAL OR NONRESPONDERS

J. Crowley¹, K.A. Papp², C.-H. Hong³, J. Parno⁴, A.M. Mendelsohn⁴, Q. Li⁵, N. Cichanowitz⁵, C. La Rosa⁵. ¹Bakersfield Dermatology, Bakersfield, CA, USA; ²Probit Medical Research, Waterloo, ON; ³Department of Dermatology and Skin Science, University of British Columbia and Probit Medical Research, Surrey, BC, Canada; ⁴Sun Pharmaceutical Industries, Inc., Princeton, NJ; ⁵Merck and Co., Inc., Kenilworth, NJ, USA

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.