those with BL G2A had a higher incidence of TEAEs vs those without BL G2A in the following MedDRA system organ classes (with incidence >20% in pts who were either with or without BL G2A): gastrointestinal disorders (30.9% vs 22.5%, respectively) and infections and infestations (44.1% vs 39.0%, respectively).

Conclusion: In this post hoc analysis, more pts with BL G2A were female, Asian, younger, had never smoked, and had lower BMI and elevated ESR and CRP vs those without BL G2A. G2A resolved within 6 months in most pts with RA receiving tofacitinib, while inflammation and disease activity (assessed by DAS28-4[ESR]) decreased. G2A appeared to resolve more rapidly in pts receiving tofacitinib vs those receiving PBO. These data suggest that tofacitinib for the treatment of RA can be an option for pts who have anaemia, within prescribing guidelines.¹

Table. Demographics and disease characteristics at baseline

	With baseline G2A (Hgb <10 g/dL)		Without baseline G2A (Hgb ≥10 g/dL)	
	Tofacitinib (N=152)	Placebo (N=27)	Tofacitinib (N=4584)	Placebo (N=1098)
Age group, years (%)				
18–45	40.8	63.0	27.3	24.3
>45–65	46.1	25.9	58.6	59.7
≥65	13.2	11.1	14.1	16.0
Age, years (mean [SD])	48.9 (13.1)	45.1 (13.7)	52.0 (12.0)	53.1 (12.0)
Female (%)	96.1	96.3	82.7	81.2
BMI, kg/m ² (mean [SD])	23.9 (5.3)	24.7 (7.1)	27.3 (6.5)	27.5 (6.7)
Race (%)				
White	39.5	37.0	64.4	66.9
Black	3.3	14.8	3.4	3.2
Asian	47.4	33.3	21.7	22.1
Other	9.9	14.8	10.5	7.7
Smoking status (%)				
Never smoked	85.5	85.2	65.2	56.0
Previous or current smoker	13.8	14.8	33.5	37.9
Unknown	<1.0	0.0	1.3	6.1
HAQ-DI (mean [SD])	1.7 (0.7)	1.6 (0.7)	1.5 (0.7)	1.4 (0.7)
DAS28-4[ESR], mean (SD)	6.9 (0.9)	7.0 (0.9)	6.4 (1.0)	6.3 (1.0)
Disease duration, years (mean [SD])	7.1 (7.8)	7.3 (7.0)	7.7 (7.9)	9.4 (8.6)
ESR, mm/hr (mean [SD])	77.8 (31.5)	69.7 (31.1)	49.5 (26.6)	45.4 (24.7)
CRP, mg/L (mean [SD])	39.1 (37.7)	34.7 (27.6)	17.7 (22.4)	16.0 (18.2)
RF+ (%)	73.4	65.2	72.3	68.6
Anti-CCP+ (%)	61.8	51.9	52.4	47.5
Hgb, g/dL (mean [SD])	9.4 (0.4)	9.3 (0.6)	12.8 (1.4)	12.9 (1.3)

Data were pooled from the following Phase 2, Phase 3 and Phase 3b/4 studies across the tofacitinib clinical programme: NCT00147498; NCT00413660; NCT00960440; NCT00550446; NCT00603512; NCT00687193; NCT00847613; NCT00814307; NCT00856544; NCT00853385; NCT01164579; NCT01039688; NCT00976599; NCT01059864; NCT01359150; NCT02147587; NCT02187055

Treatment groups are based on initial randomised study drug; tofacitinib was dosed at 5 or 10 mg BID

BID, twice daily; BMI, body mass index; CCP, cyclic citrullinated peptide; CRP, C-reactive protein; DAS28-4[ESR], Disease Activity Score in 28 joints, erythrocyte sedimentation rate; G2A, grade ≥2 anaemia; HAQ-DI, Health Assessment Questionnaire-Disability Index; Hgb, haemoglobin; RF, rheumatoid factor; SD, standard deviation

REFERENCES:

- [1] US Food and Drug Administration. XELJANZ® (tofacitinib) highlights of prescribing information. Available at: <http://labeling.pfizer.com/ShowLabeling.aspx?id=959> Accessed 28 January 2019.

Acknowledgement: Study sponsored by Pfizer Inc. Medical writing support was provided by Sarah Piggott of CMC Connect and funded by Pfizer Inc.

Disclosure of Interests: Burkhard Moeller Consultant for: Swissmedic Human Medicines Expert Committee Member (regulatory agency), Axel Finckh Grant/research support from: Bristol-Myers Squibb, Pfizer Inc, Consultant for: AbbVie, A2Bio, Bristol-Myers Squibb, MSD, Roche, Pfizer Inc, and UCB, Jose-Maria Alvaro-Gracia Consultant for: AbbVie, Bristol-Myers Squibb, Eli Lilly, MSD, Novartis, Pfizer Inc, Roche, Sanofi, and UCB, Speakers bureau: AbbVie, Bristol-Myers Squibb, Eli Lilly, MSD, Novartis, Pfizer Inc, Roche, Sanofi, and UCB, Godehard Scholz: None declared, Daniel Aletaha Grant/research support from: AbbVie, Bristol-Myers Squibb, and MSD, Consultant for: AbbVie, Bristol-Myers Squibb, Eli Lilly, Janssen, Medac, Merck, MSD, Pfizer Inc, Roche, and UCB, Speakers bureau: AbbVie, Bristol-Myers Squibb, Eli Lilly, Janssen, Medac, Merck, MSD, Pfizer Inc, Roche, and UCB, Francesca Biondo Shareholder of: Pfizer Inc, Employee of: Pfizer Inc, Sander Strengholt Shareholder of: Pfizer Inc, Employee of: Pfizer Inc, Jose Luis Rivas Shareholder of: Pfizer Inc, Employee of: Pfizer Inc, Carol A. Connell Shareholder of: Pfizer Inc, Employee of: Pfizer Inc, Harry Shi Shareholder of: Pfizer Inc, Employee of: Pfizer Inc

DOI: 10.1136/annrheumdis-2019-eular.399

FRI0163

TIME TO DISCONTINUATION OF TOFACITINAB IN PATIENTS WITH RHEUMATOID ARTHRITIS WITH AND WITHOUT METHOTREXATE: RESULTS FROM THE ONTARIO BEST PRACTICES RESEARCH INITIATIVE (OBRI) COHORT

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Background: Tofacitinib (TOFA) is an oral, small molecule drug which can be used as an alternative to biologic disease modifying antirheumatic drugs (bDMARDs) for rheumatoid arthritis (RA) treatment and is prescribed alone or with methotrexate (MTX).

Objectives: We aimed to evaluate the discontinuation rate of this drug, with and without concurrent MTX, with and without prior biologic use, in patients with RA using real world data from a Canadian (Ontario) observational cohort.

Methods: Patients enrolled in the Ontario Best Practices Research Initiative (OBRI) who started TOFA after its approval in Canada (June 2014) were included in the analysis. Patients were followed from TOFA initiation until discontinuation, death, lost to follow-up, or last visit, whichever came first. Time to discontinuation of TOFA, due to any reason, in patients 1) with or without concurrent MTX use; 2) with or without prior biologic use was assessed using Kaplan-Meier survival analysis.

Results: Among the 131 patients, 70 (53.4%) received TOFA without MTX and 61 (46.6%) TOFA with MTX. Mean (SD) age and disease duration were 60.2 (0.90) years and 13.7 (0.80) years, respectively. The majority were females (89.3%) and most had prior biologic use history (74.0%). At baseline, no significant differences in disease activity and sociodemographic profiles were found between the two groups of patients with and without concurrent MTX use. Discontinuation was reported in 44 (33.6%) of all TOFA patients with a median survival of 31.3 months. Overall retention of TOFA at 6, 12 and 24 months was 80.5%, 63.1% and 53.5% respectively. These findings are very similar to the results reported from the RHUMADATA registry at ACR 2018.¹ Fifteen (34.0%) patients stopped their TOFA due to non-response/loss of response, 22 (50.0%) due to adverse events, and 7 (16%) due to other reasons.

At 6 and 12 months' follow-up, more patients remained on TOFA in the 'TOFA with MTX' group (88.3% and 73.1%, respectively) compared to the 'TOFA without MTX' group (73.9% and 54.6%, respectively) (Logrank p=0.05). There was no significant difference in TOFA discontinuation between the two groups of patients with and without prior biologic use (Logrank p=0.77).

Conclusion: We found that half of the RA patients remained on TOFA 31 months after initiation. Patients also stayed on TOFA longer when they concurrently used MTX compared to TOFA without MTX.

REFERENCE:

- [1] Choquette D, Bessette L, Brown J, Haraoui B, Massicotte F, Pelletier JP, Raynauld JP, Rémillard MA, Sauvageau D, Turcotte A, Villeneuve É, Coupal L. Tofacitinib Show Similar Retention When Used with and without Methotrexate. Analysis from the Rhumadata® Clinical Database and Registry [abstract]. *Arthritis Rheumatol.* 2018; 70 (suppl 10).

Acknowledgement: Drs. Ahluwalia, V., Ahmad, Z., Akhavan, P., Albert, L., Alderdice, C., Aubrey, M., Aydin, S., Bajaj, S., Bensen, B., Bhavsar, S., Bobba, R., Bombardier, C., Bookman, A., Cabral, A., Carette, S., Carmona, R., Chow, A., Ciaschini, P., Cividino, A., Cohen, D., Dixit, S., Haaland, D., Hanna, B., Haroon, N., Hochman, J., Jaroszynska, A., Johnson, S., Joshi, R., Kagal, A., Karasik, A., Karsh, J., Keystone, E., Khalidi, N., Kuriya, B., Larche, M., Lau, A., LeRiche, N., Leung, Fe., Leung, Fr., Mahendira, D., Matsos, M., McDonald-Blumer, Midzic, I., Milman, N., H., Mittoo, S., Mody, A., Montgomery, A., Mulgund, M., Ng, E., Papneja, T., Pavlova, P., Perlin, L., Pope, J., Purvis, J., Rohekar, G., Rohekar, Ruban, T., S., Samadi, N., Shaiikh, S., Shickh, A., Shupak, R., Smith, D., Soucy, E., Stein, J., Thompson, A., Thorne, C., Wilkinson, S.

Disclosure of Interests: Mohammad Movahedi: None declared, Angela Cesta: None declared, Xiuying Li: None declared, Claire Bombardier Grant/research support from: Abbvie, Amgen, Bristol-Myers Squibb, Celgene, Eli Lilly, Hospira, Janssen, Merck, Novartis, Pfizer Inc, Roche, Sanofi, UCB, Consultant for: AbbVie, Hospira, Janssen, Merck, Novartis, Pfizer Inc, Sanofi, Speakers bureau: Roche

DOI: 10.1136/annrheumdis-2019-eular.4985