Objectives: This post hoc analysis aimed to provide information on the effect of tofacitinib 5 mg BID on laboratory values in PsA and RA patients (pts).

Methods: For analysis of pts with active PsA treated with tofacitinib 5 mg BID, data were pooled from 2 Phase 3 studies and an ongoing long-term extension (LTE) study (data cut-off, 25 January 2017; database not locked; data may change). For analysis of pts with moderate or severe RA treated with tofacitinib 5 mg BID, data were pooled from 8 Phase 2, 7 Phase 3, and 1 LTE studies (data cut-off, 2 March 2017; for LTE, database not locked; data may change). All PsA and most RA pts received a background conventional synthetic disease-modifying antirheumatic drug. Data (to Month 12) for pts receiving constant tofacitinib 5 mg BID were evaluated, comprising pts who received tofacitinib 5 mg BID across studies, either at randomisation or following switch from placebo. Pts in the placebo groups who switched to tofacitinib 5 mg BID at Month 3 were included from the time they first received tofacitinib. Pts who switched tofacitinib dose were excluded. Change from baseline in haematologic (haemoglobin, neutrophils, lymphocytes) and lipid (low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, total cholesterol, triglyceride) levels and key liver tests (bilirubin, alanine aminotransferase, aspartate aminotransferase) were analysed. Although not addressed in the product labelling, creatine kinase, creatinine and C-reactive protein levels were also assessed. Pts meeting protocol-defined discontinuation criteria for laboratory values were evaluated.

Results: The constant tofacitinib 5 mg BID group comprised 348 PsA pts and 3040 RA pts. Mean (standard error) changes/percentage changes from baseline for laboratory values are presented in the table. Laboratory values generally stabilised after 1 to 3 months, and lymphocyte levels stabilised by 24 months (data not shown). In both PsA and RA, $\leq 3.0\%$ of patients met discontinuation criteria for any laboratory values.

Conclusion: In this post hoc analysis of laboratory data with tofacitinib 5 mg BID, changes in key laboratory values were similar for PsA and RA, and discontinuations due to protocol criteria being met for laboratory values were infrequent. These results provide further information on the effect of tofacitinib on laboratory values in PsA and RA.

Acknowledgement: This study was sponsored by Pfizer Inc. Medical writing support was provided by Karleen Nicholson, PhD, on behalf of CMC Connect, a division of McCann Health Medical Communications Ltd, Macclesfield, UK, and was funded by Pfizer Inc.

Table. Changes in selected haematologic and lipid levels, key liver tests and C-reactive protein, creatine kinase and serum creatinine levels to Month 12 in the constant tofacitinib 5 mg BID group (safety analysis set)

	PsA (data cut-off, 25 January 2017) N=348						RA* (data cut-off, 2 March 2017) N=3040					
	Mean (SE) % change from baseline						Mean (SE) % change from baseline					
	BL	M1	M3	M6	M9	M12	BL	M1	M3	M6	M9	M12
Haemoglobin, g/dL	13.88 (0.07)	-0.01 (0.04)	0.00 (0.05)	-0.04 (0.07)	0.05 (0.06)	0.10 (0.05)	12.73 (0.01)	0.10 (0.02)	0.18 (0.02)	0.21 (0.02)	0.17 (0.02)	0.23 (0.02)
Neutrophils, 10 ⁹ /mm ³	4.85 (0.10)	-0.39 (0.08)	-0.31 (0.10)	-0.24 (0.12)	-0.32 (0.11)	-0.33 (0.12)	5.54 (0.04)	-0.75 (0.04)	-0.83 (0.04)	-0.80 (0.04)	-0.85 (0.04)	-0.88 (0.04)
Lymphocytes, 10 ⁹ /mm ³	1.84 (0.04)	0.06 (0.03)	-0.03 (0.05)	-0.05 (0.04)	-0.05 (0.04)	-0.11 (0.04)	1.83 (0.01)	0.06 (0.01)	0.01 (0.01)	0.01 (0.01)	0.04 (0.01)	-0.13 (0.01)
Bilirubin, mg/dL	0.46 (0.01)	0.03 (0.01)	0.05 (0.01)	0.04 (0.01)	0.05 (0.01)	0.05 (0.01)	0.41 (0.01)	0.02 (0.01)	0.04 (0.01)	0.05 (0.01)	0.05 (0.01)	0.05 (0.01)
ALT, IU/L	25.30 (0.91)	1.19 (0.81)	2.95 (0.87)	3.79 (1.00)	4.13 (1.11)	3.39 (1.08)	20.90 (0.20)	2.30 (0.22)	3.14 (0.35)	3.58 (0.34)	4.27 (0.42)	4.81 (0.61)
AST, IU/L	21.92 (0.57)	1.67 (0.48)	2.72 (0.55)	2.81 (0.63)	2.65 (0.74)	2.92 (0.75)	20.60 (0.18)	2.64 (0.26)	3.64 (0.24)	4.43 (0.26)	4.80 (0.29)	5.34 (0.38)
CRP, mg/L	12.09 (1.05)	-2.20 (0.89)	-4.16 (1.06)	-7.25 (1.20)	-7.56 (1.30)	-8.18 (1.41)	18.46 (0.15)	-1.70 (0.42)	-1.77 (0.45)	-12.12 (0.47)	-12.31 (0.47)	-12.11 (0.49)
Creatine kinase, U/L	99.87 (3.64)	36.37 (3.59)	50.57 (3.47)	51.69 (4.17)	54.13 (4.45)	70.14 (6.28)	31.76 (1.29)	46.96 (1.63)	50.50 (1.78)	50.60 (2.51)	66.42 (10.11)	61.47 (2.32)
Serum creatinine, mg/dL	0.81 (0.01)	0.02 (0.01)	0.02 (0.01)	0.03 (0.01)	0.03 (0.01)	0.04 (0.01)	0.73 (0.01)	0.04 (0.01)	0.04 (0.01)	0.06 (0.01)	0.06 (0.01)	0.07 (0.01)
	Mean (SE) % change from baseline						Mean (SE) % change from baseline					
	BL	M1	M3	M6	M9	M12	BL	M1	M3	M6	M9	M12
	BL	M1	M3	M6	M9	M12	BL	M1	M3	M6	M9	M12
LDL-c, mg/dL	117.52 (1.76)	7.39 (1.00)	8.43 (1.13)	9.91 (1.32)	10.35 (1.55)	10.99 (1.89)	113.70 (0.62)	10.96 (0.51)	13.85 (0.58)	14.08 (0.78)	13.93 (0.82)	15.02 (0.62)
HDL-c, mg/dL	35.59 (0.92)	9.55 (0.99)	10.34 (1.13)	9.94 (1.22)	9.67 (1.39)	10.13 (1.46)	38.92 (0.31)	13.06 (0.41)	13.97 (0.50)	13.21 (0.44)	13.87 (0.63)	13.98 (0.52)
Total cholesterol, mg/dL	201.39 (2.18)	7.68 (0.68)	7.92 (0.80)	8.72 (0.87)	8.98 (1.01)	9.33 (1.22)	197.51 (0.76)	9.90 (0.32)	12.10 (0.37)	12.18 (0.34)	13.20 (0.45)	13.33 (0.39)
TG, mg/dL	145.82 (5.55)	8.59 (2.32)	8.71 (2.24)	10.21 (2.50)	14.22 (2.93)	16.67 (3.44)	125.44 (1.24)	8.25 (0.87)	12.90 (0.95)	14.21 (0.90)	18.26 (1.45)	16.38 (1.07)

*Includes OPAL Broaden (NCT0187666; 12-month study), OPAL Beyond (NCT01882439; 6-month study) and OPAL Balance (NCT01976364; LTE study; data cut-off, 25 January 2017) studies. All studies were complete except for the LTE study. Includes studies A3921019 (NCT00147498), A3921024 (NCT0013699; LTE study; data cut-off, March 2, 2017), A3921025 (NCT0013660), A3921032 (NCT0060440), A3921035 (NCT0055046), A3921044 (NCT0066161), A3921045 (NCT00814307), A3921046 (NCT0085644), A3921064 (NCT0085338), A3921068 (NCT0164579), A3921069 (NCT0103688), A3921073 (NCT00976599), A3921109 (NCT01059864), A3921129 (NCT01359150), A3921187 (NCT0187055) and A3921237 (NCT01247587). All studies were complete except for the LTE study.

Safety analysis set: patients who received ≥ 1 dose of tofacitinib.

Baseline is the latest pre-tofacitinib dose measurement, and includes patients with a baseline and ≥ 1 post-baseline measurement.

Constant tofacitinib 5 mg BID: patients assigned to tofacitinib 5 mg BID, or advanced from placebo to tofacitinib 5 mg BID in the index studies, where Day 1 is the date of tofacitinib 5 mg BID, and includes data from LTE studies when exposure in index studies is ≤ 12 months.

ALT, alanine aminotransferase; AST, aspartate aminotransferase; BID, twice daily; BL, baseline; CRP, C-reactive protein; HDL-c, high-density lipoprotein cholesterol; LDL-c, low-density lipoprotein cholesterol; LFT, long-term extension; M, month; N, number of patients included in the analyses; Number of patients for each laboratory parameter at each visit may be fewer than N due to missing values; PsA, psoriatic arthritis; RA, rheumatoid arthritis; SE, standard error; TG, triglyceride.

Figure 1

Disclosure of Interests: William Rigby Consultant for: Pfizer Inc, Gerd Rüdiger Burmester Consultant for: Roche, Sanofi-Genzyme, Speakers bureau: Roche, Sanofi-Genzyme, Oliver FitzGerald: None declared, Valderilio F Azevedo Grant/research support from: AbbVie, GSK, Janssen, Merck Serono, Novartis, Pfizer Inc, UCB, Consultant for: AbbVie, GSK, Janssen, Merck Serono, Novartis, Pfizer Inc, UCB, Peter Nash Grant/research support from: AbbVie, Bristol-Myers Squibb, Eli Lilly, Janssen,

Novartis, Pfizer Inc, Roche, Sanofi, UCB, Consultant for: AbbVie, Bristol-Myers Squibb, Eli Lilly, Janssen, Novartis, Pfizer Inc, Roche, Sanofi, UCB, Speakers bureau: AbbVie, Bristol-Myers Squibb, Eli Lilly, Janssen, Novartis, Pfizer Inc, Roche, Sanofi, UCB, Daniela Graham Shareholder of: Pfizer Inc, Employee of: Pfizer Inc, Cunshan Wang Shareholder of: Pfizer Inc, Employee of: Pfizer Inc, Thomas Jones Shareholder of: Pfizer Inc, Employee of: Pfizer Inc

DOI: 10.1136/annrheumdis-2019-eular.1290

AB0441

THERAPY WITH TOFACITINIB IN A COLOMBIAN POPULATION WITH RHEUMATOID ARTHRITIS: RESULTS OF THE DAILY CLINICAL PRACTICE

Wilmer Gerardo Rojas Zuleta¹, Oscar Jair Felipe Díaz¹, Claudia Lucía Giraldo Herrera², Adelis Enrique Pantoja Marquez¹, Natalia Duque Zapata¹, Monica Vasquez Jaramillo¹, Catalina Orozco Gonzalez¹, Jorge Hernando Donado Gómez¹. ¹Medicare, Antioquia, Medellín, Colombia; ²Calí, Valle del Cauca, Cali, Colombia

Background: Rheumatoid arthritis (RA) is a chronic inflammatory disease that affects the quality of life and reduces life expectancy. It is characterized by the presence of autoantibodies and erosive synovitis that mainly involves small joints (1). Tofacitinib is the first oral Janus Kinase (JAK) inhibitor approved in 2012 for the treatment of patients with active, moderate to severe RA that does not respond to other therapies (2).

Objectives: The objective was to describe demographic and clinical results of a cohort of Colombian patients with RA treated with tofacitinib.

Methods: Descriptive observational study of a historical cohort of RA patients in a specialized center for the management of inflammatory arthropathies, from April 2014 to February 2018. The following variables are described: age, sex, time evolution of the disease, type of AR, comorbidities, disease activity (DAS-28), schedule and treatment time. For the descriptive analysis, categorical variables are presented as absolute and relative frequencies; while continuous variables are presented as mean and standard deviation (SD) or median and interquartile range (IQR) according to distribution. The outcome of DAS 28 ≤ 3.2 was estimated by incidence rate, defined as the number of patients who presented the outcome divided by the summation of total exposure time of the patients.

Results: Of 59 patients included, 88.1% (52) were women, with a median age of 58.8 years (IQR 49-68 years), 74.6% were seropositive, the median time from diagnosis was 18.2 years (IQR 12- 28.3 years). High blood pressure was the most common comorbidity (40.7%) and 7% had tuberculosis history. The median number of bDMARD prior to tofacitinib was 2 (IQR 1-3). Sixty six percent patients (39) were on monotherapy while 34% (20) were on combination with leflunomide (19) and methotrexate (1). The median time of treatment was 1.2 years (IQR 0.6-2 years). At the beginning, 84.7% patients (50) were in moderate or high disease activity and 15.3% (9) in remission or low activity; at the end of follow-up, 47.5% (28) were in remission or low activity and 52.5% (31) in moderate or high activity (p = 0.000). The mean DAS28 at the beginning of tofacitinib was 4.6 ± 1.55 and at the end of the follow-up was 3.5 ± 1.49 , with a difference of means of 1.10 (IC95% 0.62-1.57), (p 0.00). During the follow-up period, the rate of development of remission or low activity was 11.92 (95% CI 8.35-16.51) cases per 100 people-month observed (p 0.00). Only 2 patients developed therapeutic failure.

Conclusion: Tofacitinib shows a good profile of effectiveness in patients with failure to prior bDMARD. Almost 50% patient reaches low disease activity or remission during follow up and low number of therapeutic failure was found.

REFERENCES

- Picchianti-Diamanti A, et al. Front Microbiol. 2018;8(2696):1-9
- Cohen S, et al. Rheumatol Ther. 2018;5(1):283-291

Disclosure of Interests: Wilmer Gerardo Rojas Zuleta Speakers bureau: Bristol-Myers Squibb, Novartis, Janssen, Pfizer, Oscar Jair Felipe Díaz Speakers bureau: Bristol-Myers Squibb, Novartis, Janssen, Pfizer, Claudia Lucía Giraldo Herrera Speakers bureau: Novartis, Abbvie, Adelis Enrique Pantoja Marquez: None declared, Natalia Duque Zapata: None declared, Monica Vasquez Jaramillo: None declared, Catalina Orozco Gonzalez: None declared, Jorge Hernando Donado Gómez: None declared

DOI: 10.1136/annrheumdis-2019-eular.5552