Bio-switch	adjusted OR (95% CI)	p-value
Age	0.990 (0.952-1.029)	0.608
Male	1.010 (0.294-3.475)	0.987
RF positive	0.481 (0.151-1.532)	0.216
Concomitant MTX	1.120 (0.459-2.731)	0.803
Concomitant PSL	0.496 (0.202-1.221)	0.127
DAS28-CRP	0.603 (0.432-0.843)	0.003
20% improvement of MMP-3 @12weeks	3.550 (1.454-8.666)	0.005

Conclusion: In the bio-switch patients, we sometimes have difficulty to obtain good clinical response of abatacept and it would be even more important to judge whether to continue abatacept or whether to add other anti-rheumatic drugs as early as possible [3]. Our results suggested that the improvement of MMP-3 at 12 weeks would be a key to predict good clinical effectiveness of abatacept at 1 year. We would be better to note not only the major clinical indices such as DAS28 but also the change of MMP-3 to obtain the best clinical results in the bio-switch patients treated with abatacept.

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REAL-WORLD SAFETY DATA FROM PATIENTS WITH RHEUMATIC DISEASES TREATED WITH CT-P13, AN INFILIXIMAB BIOSIMILAR: AN INTERIM ANALYSIS FROM AN OBSERVATIONAL STUDY

Peter C. Taylor¹, Robin Christensen², Shahrzad Moosavi³, Pamela Selema³, Ruffy Guilato⁴, Heather Fowler⁵, Claire Bombardier⁶, Boulos Haraoui⁷. ¹University of Oxford, Oxford, United Kingdom; ²The Parker Institute, Copenhagen and Odense University Hospital, Copenhagen, Denmark; ³Pfizer Inc, New York City, United States of America; ⁴Pfizer Inc, Manila, Philippines; ⁵Pfizer Inc, Maidenhead, United Kingdom; ⁶UHN/MSH, Toronto, Canada; ⁷University of Montreal, Montreal, Canada

Background: CT-P13, an infliximab biosimilar, has been available in Europe and Canada since 2015, and real-world experience with CT-P13 is important to support the safety of this medication. PERSIST is an ongoing, observational cohort study evaluating CT-P13 as treatment for rheumatoid arthritis (RA), ankylosing spondylitis (AS) and psoriatic arthritis (PsA) in a real-world setting.

Objectives: This interim analysis reports safety outcomes for patients who received CT-P13 as their first biologic (Biologic-naïve) or who switched from infliximab reference product (IFX-RP) to CT-P13 (Switched) based on data collected from September 2015 to December 2017.

Methods: Patients were recruited during usual care at 38 academic and community sites in 6 European countries and Canada. Adult RA, AS or PsA patients prescribed CT-P13 or locally-sourced IFX-RP at the investigator's discretion and according to the approved label were eligible. Data were analysed descriptively.

Results: This analysis included 329 patients (RA, n=134; AS, n=110; PsA, n=85). Of these, 6 (1.8%) were not treated, 3 (0.9%) completed study treatment, 244 (74.2%) were ongoing and 76 (23.1%) discontinued study treatment, most commonly due to lack of response (30 [9.1%]). Demographics and baseline characteristics were generally similar between groups (Table 1). Most treatment-emergent adverse events (TEAEs; Table 2) were of mild or moderate intensity; 7/129 events were severe. Most commonly reported adverse events were related to infection (n=33; 10.2%); most frequently reported infection-related TEAEs were nasopharyngitis (n=6; 1.9%), respiratory tract infection (n=5; 1.5%) and pneumonia (n=4; 1.2%). No case of tuberculosis was reported. Eight (2.5%) patients reported infusion related reactions.

Table 1. Disposition, population characteristics and drug utilisation patterns for patients receiving CT-P13

	Biologic-naïve (n=216)	Switched (n=107)	Total (N=323)
Age, median (range), years	54 (19–84)	53 (23–76)	54 (19–84)
Male, n (%)	97 (44.9)	59 (55.1)	156 (48.3)
Disease duration, median (range), months	45.34 (0.03–563.91)	159.51 (12.65–464.07)	86.77 (0.03–563.91)
Baseline dose			
Patients with data for baseline dose, n	202	102	304
Mean (SD), mg/kg	3.68 (1.05)	3.96 (0.94)	3.78 (1.02)
Baseline infusion frequency, n (%)			
Once every 6 or fewer weeks	72 (33.3)	43 (40.2)	115 (35.6)
Once every 8 weeks	76 (35.2)	44 (41.1)	120 (37.2)
Other	54 (25.0)	15 (14.0)	69 (21.4)
Missing	14 (6.5)	5 (4.7)	19 (5.9)

Table 2. All-causality TEAEs for patients receiving CT-P13

	Biologic-naïve (n=216)	Switched (n=107)	Total (N=323)
Number of TEAEs	87	42	129
Patients with ≥1 event, n (%)			
TEAEs	59 (27.3)	22 (20.6)	81 (25.1)
Serious TEAEs ^a	12 (5.6)	9 (8.4)	21 (6.5)
TEAEs of special interest ^b	18 (8.3)	7 (6.5)	25 (7.7)
Discontinued from study due to adverse events	3 (1.4) ^c	0	3 (0.9)
Deaths	0	0	0

^a Difference between groups due to higher incidence of infections in switched (3.7%) vs biologic-naïve (1.4%).

^b Difference between groups due to higher incidence of infusion related reaction in biologic-naïve (6.0%) vs switched (1.9%).

^c Included hepatobiliary disease, uterine cancer, and psoriasis.

TEAE=treatment-emergent adverse event.

Conclusion: Incidences of TEAEs were similar and there was no discernible pattern across the most common TEAEs between groups. These interim analysis results from the PERSIST study conducted in a real-world setting are consistent with the known safety profile of infliximab and do not demonstrate new safety information to change the benefit-risk profile of CT-P13.

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