Real-world safety data from patients with rheumatic diseases treated with CT-P13, an infliximab biosimilar: an interim analysis from an observational study

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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.

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.

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.