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Original article

Real-life drug persistence in patients with rheumatic diseases treated with CT-P13: a prospective observational cohort study (PERSIST)

Peter C. Taylor ⬤[1], Robin Christensen[2,3], Shahrzad Moosavi[4],
Pamela Selema[4], Ruffy Guilatco[5], Heather Fowler[6], Markus Mueller[7],
Katherine F. Liau[8] and Boulos Haraoui[9]

Abstract

Objective The aim was to report results from PERSIST, a real-life, observational, prospective cohort study of CT-P13, an infliximab (IFX) biosimilar, for treatment of patients with RA, AS or PsA who were biologic naïve or switched from an IFX reference product (IFX-RP; Remicade).

Methods Adult patients were recruited during usual care at 38 sites in Europe and Canada and enrolled by their physicians after meeting eligibility criteria according to the country-approved label for CT-P13. Primary outcomes were to determine drug utilization and treatment persistence and to assess safety. Patients were followed for up to 2 years. Data were analysed and reported descriptively.

Results Of 351 patients enrolled, 334 were included in the analysis (RA, 40.4%; AS, 34.7%; PsA, 24.9%). The safety analysis set comprised all 328 patients treated with CT-P13. The majority (58.2%) of patients received CT-P13 monotherapy, most (72.6%) by dosing every 6 or 8 weeks. The mean treatment persistence was 449.2 days; 62.3% of patients completed 2 years of treatment. In all, 214 treatment-emergent adverse events (TEAEs) were reported in 38.4% of patients. Most TEAEs were of mild or moderate intensity; 13 were severe. The most commonly reported TEAEs were drug ineffective (9.5%) and infusion-related reactions (5.2%). The most frequently reported infection-related TEAEs were upper respiratory tract infections (3.0%), nasopharyngitis (2.1%) and bronchitis (1.5%). No patients experienced tuberculosis.

Conclusion Drug utilization and treatment persistence with CT-P13 were consistent with historical reports of IFX-RP in this patient population. Safety findings did not identify new concerns for CT-P13 in the treatment of patients with RA, AS or PsA.

Trial registration ClinicalTrials.gov: NCT02605642.

Key words: CT-P13, infliximab, biosimilar, PERSIST, real life, observational, persistence, safety, rheumatic diseases

<div style="writing-mode: vertical">CLINICAL SCIENCE</div>

[1]Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK,
[2]Section for Biostatistics and Evidence-Based Research, The Parker Institute, Bispebjerg and Frederiksberg Hospital, Copenhagen, [3]Research Unit of Rheumatology, Department of Clinical Research, University of Southern Denmark, Odense University Hospital, Odense, Denmark, [4]Worldwide Safety and Risk Management, Pfizer Inc., New York, NY, USA, [5]Global Biometrics & Data Management, Global Product Development, Pfizer Inc., Manila, Philippines, [6]Clinical Development & Operations, Global Product Development, Pfizer Inc., London, UK, [7]Medical Affairs, Pfizer Pharma GmbH, Berlin, Germany, [8]Biosimilars, Pfizer Inc., La

Jolla, CA, USA and [9]Clinical Research Unit in Rheumatology, Institut de rhumatologie de Montréal, Montreal, QC, Canada

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Correspondence to: Peter C. Taylor, Botnar Research Centre, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Windmill Road, Headington, Oxford OX3 7LD, UK. Email: peter.taylor@kennedy.ox.ac.uk

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Key messages

- CT-P13, an infliximab biosimilar, was evaluated in a real-life, prospective, observational cohort study.
- The cohort comprised both biological DMARD-naïve RA, AS and PsA patients and those switched from reference infliximab (Remicade).
- Drug utilization, persistence and safety of CT-P13 were consistent with the established reference infliximab profile.

Introduction

Rheumatic diseases, including RA, AS and PsA, are a leading cause of disability and impose a considerable patient and health-care burden [1]. Recognition of the benefits of early diagnosis and therapy, particularly with DMARDs, has improved outcomes for patients. More specifically, biologic DMARDs (bDMARDs), such as TNF-α inhibitors, have played a pivotal role in disease management, including in those patients who are unresponsive to conventional synthetic DMARDs [2–4]. Infliximab (IFX) is a monoclonal antibody TNF-α inhibitor that has been used successfully in the treatment of RA, AS, PsA and other inflammatory conditions, including plaque psoriasis, ulcerative colitis and Crohn's disease [5–8].

Biosimilars are biologic drugs that have been developed and approved by meeting the same quality standards as their reference licensed bDMARDs, with equivalent, clinically proven efficacy and safety profiles [9–11]. The potential for biosimilars to be made available at a lower price than their reference originator can reduce overall health-care costs [12]. The clinical profile of biosimilars coupled with the opportunity to apply these potential savings in expanding patient access to treatment is a significant motivation for patients being switched to biosimilars [13]. CT-P13 [Inflectra (infliximab-dyyb), Pfizer Inc., New York, NY, USA; Remsima, Celltrion Healthcare Hungary Kft, Budapest, Hungary] is an IFX biosimilar that has the same amino acid sequence and higher order structure as the IFX reference product (IFX-RP; Remicade, Janssen Biotech, Horsham, PA, USA; Janssen Biologics B.V., Leiden, The Netherlands) [14]. CT-P13 is approved for all eligible indications of IFX-RP in Europe [15], the USA [16], Canada [17], Australia [18], Japan [19] and many other countries. Approval of CT-P13 was based on an extensive biosimilar development programme conducted in line with regulatory guidance within each region, in which CT-P13 demonstrated equivalent quality, efficacy and safety in its preclinical, pharmacokinetic/pharmacodynamic and clinical programmes to those of IFX-RP [14, 20–22].

With the wider availability and growing use of CT-P13, obtaining information on treatment patterns, including treatment persistence and drug utilization in real-world settings, has been important in informing treatment management and maintenance decisions towards optimizing clinical experience with CT-P13 [23, 24].

Here, we report findings from a real-life, international multicentre, prospective observational cohort study (PERSIST), with the aim of evaluating drug-utilization patterns and the persistence and safety of CT-P13 in the treatment of patients with RA, AS or PsA, including those who were biologic naïve or switched treatment from IFX-RP to CT-P13. A subset of safety data from PERSIST has been presented previously as part of a pooled safety analysis of six global, real-world, post-marketing studies of CT-P13 in immune-mediated inflammatory diseases [25].

Methods

Study design

PERSIST [prospective observational cohort study to assess persistence of CT-P13 (infliximab) in patients with rheumatoid diseases who are either naïve to biologics or switched from stable Remicade (infliximab)] was registered at ClinicalTrials.gov (NCT02605642) and conducted in accordance with local legal and regulatory requirements. The final protocol, any amendments and informed consent documentation were reviewed and approved by an institutional review board and/or independent ethics committee at each site participating in the study. A signed and dated informed consent form was required before enrolment.

The decision to initiate treatment with CT-P13, or to switch from IFX-RP to CT-P13, was at the physician's discretion. Treatment was provided according to the prescribing recommendations in the respective country [15, 17]. Scheduled patient visits followed the local standard of care, typically coinciding with the schedule of infusions of CT-P13, with additional visits as needed for usual patient care. No additional study visits were mandated according to the study protocol. The original protocol was amended once. Details of the amendments and the final study protocol can be found at ClinicalTrials.gov (https://clinicaltrials.gov/ct2/show/NCT02605642).

Patient population

Patients ≥18 years of age at enrolment who had a diagnosis of RA, AS or PsA were recruited during usual care visits at 38 academic and community sites in six European countries (Bulgaria, Czech Republic,

Germany, Greece, Spain and the UK) and Canada. All patients were expected to be enrolled over a ~16-month period, with each patient followed for up to 2 years. Patients who discontinued treatment permanently were encouraged to remain in the study and were followed for the remainder of the study period. Eligible patients were bDMARD naïve and prescribed CT-P13 or had switched from IFX-RP to CT-P13 at the investigator's discretion, following the prescribing information from the European Union's Summary of Product Characteristics (SmPC) [15] or Health Canada's Product Monograph [17]. Key exclusion criteria comprised any reported contraindications for CT-P13 according to the SmPC [15] or Product Monograph [17], or known hypersensitivity (including severe, acute infusion reactions) to IFX, its excipients or other murine proteins, at the time of enrolment.

Primary outcomes and assessments

Treatment patterns, outcomes, vital statistics and adverse events (AEs), including serious AEs (SAEs), were collected using an electronic data-capture system. The primary outcomes were to evaluate drug-utilization patterns and drug persistence and to assess safety. Patient characteristics were also analysed. The study protocol was amended on 17 May 2017 to align the protocol template and safety reporting details with Pfizer's processes following its acquisition of Hospira, including an update made to the Statistical Analysis Plan on 28 November 2017 [details available at ClinicalTrials.gov (https://clinicaltrials.gov/ProvidedDocs/42/NCT02605642/SAP_001.pdf)], to include non-serious AEs as part of the safety evaluation. This update was not applied retrospectively; therefore, non-serious AEs were captured only from the implementation of the amended protocol and not for the entire study.

Population characteristics included demographic and baseline characteristics (age, sex, race, height, weight and body mass index), medical history, disease duration (number of months from initial diagnosis of rheumatoid disease to the date of informed consent) and surgery status. The drug-utilization pattern included the infusion frequency of CT-P13, concomitant medications (CSs, NSAIDs, immunosuppressants or other medications) related to the treatment of RA, AS or PsA at the time of enrolment, and ongoing concomitant medications [according to World Health Organization Drug Enhanced B2 Index (September 2018)]. Persistence was defined as the time from index date (date of CT-P13 initiated during the 2-year observation study period) until drug discontinuation [i.e. either switching to another non-IFX bDMARD or the elapse of a drug-free interval ≥16 weeks (i.e. two skipped doses)].

Patients who discontinued IFX treatment were followed for the remainder of the 2-year observation study period using a simplified case report form. For the treatment-discontinuation visit, the reasons for discontinuation, concomitant medications and AEs were collected. All treatment-emergent AEs (TEAEs), including treatment-emergent SAEs (TESAEs) and treatment-emergent

AEs of special interest (TEAESIs), were coded and summarized according to the Medical Dictionary for Regulatory Activities version 21.1, system organ class (SOC) and preferred term (PT).

Statistical analysis

The original plan of the study was to enrol ~1500 patients, with ~650 enrolled patients switched to CT-P13 from IFX-RP treatment and the remainder anticipated to be bDMARD naïve. The statistical analysis and reporting were descriptive in nature owing to the observational design of the study. Descriptive statistics included the number of observations, mean, median, standard deviation, minimum and maximum for all continuous variables. For categorical variables, numbers of observations and percentages were provided. For AEs, patients who experienced more than one AE within a given SOC or PT were counted once within that SOC or PT. Exposure-adjusted incidence rates were not generated for the study; only crude incidence rates were reported. Primary analyses were conducted on the safety analysis population, which consisted of all patients who received at least one dose of study drug.

Results

Population characteristics and drug-utilization patterns

After 18 months of enrolment, 351 patients had been recruited. At that time, recruitment to the study was closed in accordance with the originally planned enrolment deadline (31 December 2016). In view of the smaller than planned patient sample size, the subgroups of bDMARD-naïve patients prescribed CT-P13 ($n = 215$) and those switched to treatment CT-P13 from IFX-RP ($n = 107$) were considered too small to make any formal comparisons. Given that all patients were treated with CT-P13 during the study period, only the pooled data for the overall population are presented.

Of the 351 enrolled patients, 17 who had switched to CT-P13 from a bDMARD other than IFX-RP were excluded from the final analysis. Of the remaining 334 patients, 40.4% ($n = 135$) had a diagnosis of RA, 34.7% ($n = 116$) had a diagnosis of AS and 24.9% ($n = 83$) had a diagnosis of PsA. Six patients were not treated owing to patient withdrawal or lack of reimbursement approval. Therefore, a total of 328 patients were treated with CT-P13 and were included in the safety analysis set.

A summary of the demographics and baseline characteristics of the overall population ($n = 328$) is presented in Table 1. In total, 49.4% ($n = 162$) of the patients were men, and most [97.0% ($n = 318$)] patients were White. Approximately 10% ($n = 32$) of patients had undergone prior surgery relevant to their underlying condition. At baseline, the reported infusion frequency for most patients was once every 6 (36.9%) or 8 weeks (35.7%). In patents with AS, a higher proportion of patients reported a 6-week infusion frequency (43.1%) compared

TABLE 1 Population characteristics and drug-utilization patterns for patients receiving CT-P13 (safety analysis set)

Variable	All patients (N = 328)
Population characteristics	
Age, median (range), years	54 (19–84)
Male, *n* (%)	162 (49.4)
Race, *n* (%)	
White	318 (97.0)
Black or African American	2 (0.6)
Asian	6 (1.8)
Other	2 (0.6)
Country, *n* (%)	
Bulgaria	19 (5.8)
Canada	71 (21.7)
Czech Republic	30 (9.2)
Germany	153 (46.7)
Greece	10 (3.1)
Spain	14 (4.3)
UK	31 (9.5)
Disease type, *n* (%)[a]	
RA	135 (40.4)
AS	116 (34.7)
PsA	83 (24.9)
Disease duration, median (range), months	86.8 (0.03–564)
Surgery status, *n* (%)	
Yes	32 (9.8)
No	296 (90.2)
Drug utilization	
Baseline infusion frequency, *n* (%)	
Once every 4 weeks	4 (1.2)
Once every 6 weeks	121 (36.9)
Once every 8 weeks	117 (35.7)
Other	67 (20.4)
Duration of drug exposure, mean (s.d.), days	528.2 (244.59)
Medications related to treatment of RA, AS or PsA, *n* (%)	
None	191 (58.2)
CSs	30 (9.1)
NSAIDs	32 (9.8)
Immunosuppressants	60 (18.3)
Other	28 (8.5)
Missing	12 (3.7)

[a]Final analysis set.

with dosing every 8 weeks (27.6%), whereas in patients with PsA, 29.9% and 46.8% of patients reported an every 6-week and 8-week dosing frequency, respectively. The mean duration of drug exposure was 528.2 days.

Overall, of 328 patients, 14.6% ($n = 48$) required at least one change in CT-P13 dose during the study. Among 92.4% ($n = 303$) of patients who took at least one concomitant medication, the most commonly reported medications by drug class were immunosuppressants [57.6% ($n = 189$)], anti-inflammatory and anti-rheumatic products [44.8% ($n = 147$)], CSs for systemic use [29.3% ($n = 96$)] and supplemental preparations, including folic acid [24.4% ($n = 80$)] (Supplementary Table S1, available at *Rheumatology Advances in Practice* online). The majority of patients in each disease population were reported to have taken concomitant medications:

RA [97.8% ($n = 132$)], AS [86.2% ($n = 100$)] and PsA [92.2% ($n = 71$)]. Among all patients, 58.2% ($n = 191$) received CT-P13 alone and took no other medications related to the treatment of RA, AS or PsA, whereas 9.1% ($n = 30$) of patients received CSs, and 18.3% ($n = 60$) received immunosuppressants (Table 1). Among patients with RA, AS and PsA, respectively, 55.6% ($n = 75$ of 135), 64.7% ($n = 75$ of 116) and 53.2% ($n = 41$ of 77) received CT-P13 alone for the treatment of their disease (Supplementary Table S2, available at *Rheumatology Advances in Practice* online). The proportions of patients with RA, AS and PsA who received CSs were 16.3% ($n = 22$ of 135), 3.4% ($n = 4$ of 116) and 5.2% ($n = 4$ of 77), respectively; 23.0% ($n = 31$ of 135), 11.2% ($n = 13$ of 116) and 20.8% ($n = 16$ of 77) of patients with RA, AS and PsA, respectively, received immunosuppressants

Persistence

The mean treatment persistence with CT-P13 by the end of study was 449.2 days (S.D. 291.02 days). The median (range) persistence was 609.5 (1–732) days. The time to treatment discontinuation is shown in Fig. 1. Of 334 patients in the study, 62.3% ($n = 208$) completed 2 years of treatment and 35.9% ($n = 120$) discontinued treatment. Among patients with RA, AS and PsA, 60.7% (82 of 135), 66.4% (77 of 116) and 59.0% (49 of 83), respectively, completed treatment. At the end of the study, 47.9% of patients continued with CT-P13 treatment (Table 2). Treatment persistence with CT-P13 during the study by disease type is shown in Supplementary Table S3, available at *Rheumatology Advances in Practice* online.

Overall, the most frequent reasons for discontinuation from treatment were lack of response or disease flare [13.2% ($n = 44$)], patient's decision to stop treatment [4.5% ($n = 15$)] and patient's withdrawal of consent [4.2% ($n = 14$)]. Among RA patients who discontinued treatment because of loss of efficacy and perceived harm, respectively, 13 of 17 and 21 of 34 received CT-P13 monotherapy compared with 3 of 17 and 11 of 34 who received immunosuppressants or CSs. A higher proportion of patients who discontinued treatment because of loss of efficacy and perceived harm, respectively, reported receiving treatment every 8 weeks [40.9% ($n = 18$ of 44) and 40.0% ($n = 32$ of 80)] *vs* by 6-week dosing [18.2% ($n = 8$ of 44) and 23.8% ($n = 19$ of 80)], at baseline.

Overall, 65.0% ($n = 217$) of patients completed follow-up to the end of the 2-year observation study period, and 35.0% ($n = 117$) discontinued from the study.

Safety

Overall, 214 all-causality TEAEs were reported by 38.4% ($n = 126$ of 328) of patients (Table 3). Among patients with RA, AS and PsA, respectively, 41.5% ($n = 56$ of 135), 36.2% ($n = 42$ of 116) and 36.4% ($n = 28$ of 77) reported all-causality TEAEs. The most commonly reported TEAEs overall (as a percentage of 328 patients)

Fig. 1 Kaplan–Meier curve for time to drug discontinuation (safety analysis set)

| Number at risk | 328 | 261 | 227 | 210 | 186 | 172 | 165 | 125 |
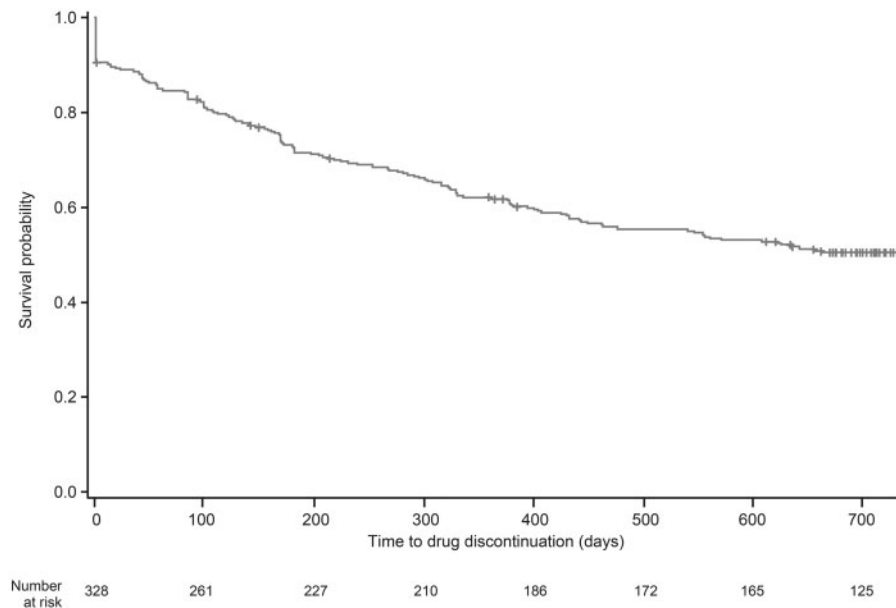
Patients who were lost to follow-up or were treated continuously with CT-P13 at the end of the observation period were censored. Results are based on persistence with CT-P13 treatment during the study 2-year observation period (in days).

TABLE 2 Treatment persistence with CT-P13 during the study

	All patients (*N* = 328)
Persistence, days[a]	
Mean (S.D.)	449.2 (291.02)
Median (range)	609.5 (1–732)
Patients who persisted with CT-P13 at the end of the study, %	47.9

[a]Using first CT-P13 treatment during the 2-year observation period as reference.

TABLE 3 All treatment-emergent adverse events (system organ class and preferred term ≥1.0% overall) in patients receiving CT-P13 (safety analysis set)

Treatment-emergent adverse events	All patients (N = 328)
Number of reported AEs	214
Patients with at least one AE, *n* (%)	126 (38.4)
Gastrointestinal disorders	6 (1.8)
General disorders and administration-site conditions	38 (11.6)
Drug ineffective	31 (9.5)
Hepatobiliary disorders	5 (1.5)
Infections and infestations	44 (13.4)
Bronchitis	5 (1.5)
Herpes zoster	4 (1.2)
Nasopharyngitis	7 (2.1)
Pneumonia	4 (1.2)
Upper respiratory tract infection	10 (3.0)
Injury, poisoning and procedural complications	21 (6.4)
Infusion-related reaction	17 (5.2)
Investigations	6 (1.8)
Musculoskeletal and connective tissue disorders	18 (5.5)
Neoplasms benign, malignant and unspecified (including cysts and polyps)	4 (1.2)
Nervous system disorders	12 (3.7)
Headache	6 (1.8)
Skin and subcutaneous tissue disorders	6 (1.8)
Vascular disorders	5 (1.5)

AE: adverse event.

were drug ineffective [9.5% (*n* = 31)] and infusion-related reactions [5.2% (*n* = 17)] (Table 3). TEAEs related to infections and infestations occurred in 13.4% (*n* = 44) of all treated patients, with the most frequently reported being attributable to upper respiratory tract infections [3.0% (*n* = 10)], nasopharyngitis [2.1% (*n* = 7)] and bronchitis [1.5% (*n* = 5)]. No patients experienced tuberculosis. There were no major differences across patients with RA, AS and PsA in the frequencies of individual TEAEs (not shown). A total of 72 (22.0%) patients experienced TEAEs considered by the investigator to be treatment related.

Overall, 29 of 328 (8.8%) patients experienced TESAEs. The most frequently reported TESAEs were bronchitis, OA and herpes zoster [each occurring in 0.6% (*n* = 2) of patients; Table 4]. No deaths were reported in the study.

The incidence of discontinuation (Table 5) from the study attributable to AEs in the overall population was 12.8% (*n* = 42 patients). Drug ineffective [6.7% (*n* = 22) of patients] and infusion-related reaction [3.4% (*n* = 11) of patients] were the most frequently reported AEs leading to study discontinuation.

Most TEAEs were mild (118) or moderate (80) in severity. Thirteen severe TEAEs were reported in 3.0% (*n* = 10 of 328) of patients; three patients had more than one TEAE with the same PT but different severities, and only the most severe TEAE was counted. Except for a severe treatment-related SAE of uveitis and one of necrotizing herpetic retinopathy, all severe treatment-related SAEs resolved. The numerical differences in the rate of severe TEAEs in the different disease populations [3.7% (*n* = 5 of 135), 3.4% (*n* = 4 of 116) and 1.3% (*n* = 1 of 77) in RA, AS and PsA patients, respectively] were not considered clinically meaningful. Overall, 9.8% (*n* = 32) of patients reported TEAESIs. The most frequently reported TEAESIs overall were those related to infusion-related reactions [5.5% (*n* = 18)] and to serious infections [2.4% (*n* = 8)]. There were no notable risk factors documented for patients who experienced serious infections.

Discussion

The PERSIST study provided data on the use of CT-P13 in the treatment of patients with RA, AS or PsA in a real-life setting, including patients not previously treated with biologic therapy and those switching from treatment with IFX-RP. The mean treatment persistence with CT-P13 was 449.2 days out of a 2-year observation study period. Overall, 47.9% of patients continued with CT-P13 beyond the end of the 2-year follow-up period, comprising 44.4%, 50.0% and 50.6% of the patients with RA, AS and PsA, respectively.

The effects of switching from IFX-RP to CT-P13 are of interest; however, the clinical studies that composed the

TABLE 4 All treatment-emergent serious adverse events (system organ class and preferred term >0.5% in any group) in patients receiving CT-P13 (safety analysis set)

Treatment-emergent serious adverse events	All patients (N = 328)
Number of reported serious AEs	34
Patients with at least one serious AE, n (%)	29 (8.8)
Cardiac disorders	2 (0.6)
Hepatobiliary disorders	2 (0.6)
Infections and infestations	10 (3.0)
Bronchitis	2 (0.6)
Herpes zoster	2 (0.6)
Injury, poisoning and procedural complications	2 (0.6)
Musculoskeletal and connective tissue disorders	3 (0.9)
OA	2 (0.6)
Neoplasms benign, malignant and unspecified (including cysts and polyps)	3 (0.9)
Nervous system disorders	2 (0.6)
Vascular disorders	2 (0.6)

AE: adverse event.

TABLE 5 Patients discontinuing from study owing to treatment-emergent adverse events (system organ class and preferred term >0.5% in any group) (safety analysis set)

Treatment-emergent adverse events	All patients (N = 328)
Number of reported AEs leading to discontinuation	43
Patients with at least one AE leading to study discontinuation, n (%)	42 (12.8)
General disorders and administration-site conditions	22 (6.7)
Drug ineffective	22 (6.7)
Hepatobiliary disorders	2 (0.6)
Infections and infestations	2 (0.6)
Injury, poisoning and procedural complications	12 (3.7)
Infusion-related reaction	11 (3.4)
Skin and subcutaneous tissue disorders	3 (0.9)

AE: adverse event.

development programme for CT-P13 were not designed to evaluate switching between therapies, and the patients were naïve to biologic therapy [20, 21]. There are a number of studies reporting on the real-life switching from IFX-RP to CT-P13 [26–30] in patients with rheumatic diseases. For instance, the DANBIO registry in Denmark recorded the impact on disease activity and retention rates following a nationwide non-medical switch from IFX-RP to CT-P13 in patients with RA, PsA and axial spondyloarthritis (AxSpA) [27]. The study indicated that switching to CT-P13 had no negative impact on disease activity, and 84% of patients still remained on therapy at 1 year, with the retention rate for patients with RA (81%) being lower than for those with PsA (86%) or AxSpA (87%) [27]. In a French single-centre cohort study of a mixed population of 260 patients (including those with RA, AxSpA and IBD) administered maintenance therapy with IFX-RP who were systematically switched to CT-P13, 77% of patients were still on treatment at the last study visit

(mean follow-up 34 weeks) [26]. The retention rate was significantly lower in patients with rheumatic disease [74% (n = 134 of 182)] compared with those with IBD [86% (n = 67 of 78), P = 0.034] [26], which might reflect the wider range of alternative biologic treatment options (including s.c. formulations) for use in rheumatology compared with the gastroenterology setting. Among patients with a clinical diagnosis of RA, AS or PsA in four rheumatology departments in The Netherlands who agreed to switch from IFX-RP to CT-P13 (the BIO-SWITCH study), 76% of patients continued treatment during 6 months of follow-up, wherein the subjective assessment of change in disease activity or AEs was the main reason for discontinuation [28].

The safety profile of patients treated with CT-P13 in the present study is consistent with the known safety profile of IFX [7]. Moreover, there was no difference in the safety profile of CT-P13 between disease populations. Other than drug ineffective, the most commonly

reported TEAEs were infusion-related reactions and related to infections. The most commonly reported TESAEs were related to infections. The incidence rates for infusion-related reactions and infections were consistent with the rates reported with IFX-RP [5]. There were no cases of tuberculosis, and no deaths were reported in the study. The most common reasons for discontinuation from the study owing to AEs were drug ineffective and infusion-related reactions.

Limitations or potential biases inherent in this non-interventional, observational cohort study included the fact that the study protocol did not mandate treatments, nor did it dictate which medical information should be entered into patient charts. Rather, each participating site provided and documented patient care and outcomes according to usual care, physician discretion and local practice standards. Not all study variables were available for all patients at all data-collection time points, especially if data were not recorded in the chart according to routine medical care. At closure of enrolment into the study at the pre-specified deadline, the overall sample size was smaller than planned. Owing to the observational study design, AE reporting provided limited clinical detail. Reporting of safety information, specifically the reporting of all non-serious AEs, was initiated only after a protocol amendment while the study was ongoing; therefore, the findings reported here might not completely reflect all AEs occurring during the study.

Conclusions

In this prospective, multinational, observational study, composed of patients with RA, AS or PsA treated with CT-P13, who were bDMARD naïve or who switched from treatment with IFX-RP to CT-P13, the mean treatment persistence with CT-P13 was 449.2 days, including 47.9% of patients who continued with CT-P13 beyond the end of the 2-year follow-up period. No new safety concerns were identified to alter the established benefit–risk profile of the IFX biosimilar CT-P13, which supports its use in the treatment of patients in these disease populations. These results based on the safety analysis population were consistent with the known safety profile of IFX.

Acknowledgements

Data availability statement

Upon request, and subject to certain criteria, conditions and exceptions (see https://www.pfizer.com/science/clinical-trials/trial-data-and-results for more information), Pfizer will provide access to individual de-identified participant data from Pfizer-sponsored global interventional clinical studies conducted for medicines, vaccines and medical devices (1) for indications that have been approved in the US and/or EU or (2) in programmes that have been terminated (i.e. development for all indications has been discontinued). Pfizer will also consider requests for the protocol, data dictionary and statistical analysis plan. Data may be requested from Pfizer trials 24 months after study completion. The de-identified participant data will be made available to researchers whose proposals meet the research criteria and other conditions, and for which an exception does not apply, via a secure portal. To gain access, data requestors must enter into a data access agreement with Pfizer.

Supplementary data

Supplementary data are available at *Rheumatology Advances in Practice* online.

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