INTRODUCTION

Infliximab has an important role in the treatment of psoriatic arthritis (PsA) and is recommended by clinical guidelines. In 2013 and 2016, respectively, the intravenously (IV) administered infliximab biosimilar CT-P13 IV received regulatory approval from the European Medicines Agency (EMA) and US Food and Drug Administration for the same indications as reference infliximab. A subcutaneous (SC) formulation of CT-P13 (CT-P13 SC)—the first and only SC infliximab formulation—has since been developed, which may benefit patients and healthcare systems. Clinical trials in patients with rheumatoid arthritis and inflammatory bowel disease demonstrated the non-inferiority of CT-P13 SC to CT-P13 IV in terms of efficacy and pharmacokinetics, respectively, alongside comparable safety profiles. In July 2020, the European Commission granted an extension of the marketing authorization for CT-P13 SC to indications including PsA; this was based on extrapolation rather than clinical trial...
experience. To our knowledge, there are also no published reports of CT-P13 SC treatment for PsA in routine clinical practice.

The coronavirus disease (COVID-19) pandemic has significantly impacted care and health behavior for rheumatology patients. However, the importance of continuity in patient care and maintaining adequate disease control during the pandemic has been acknowledged. To maximize safety and protect staff from infection, April 2020 guidance from the National Institute for Health and Care Excellence (NICE) recommended that patients with rheumatological disorders receiving IV treatment should be assessed for switching to an SC form of the same treatment, or changing to an alternative SC treatment. In this case series, two patients with PsA opted to start infliximab therapy with CT-P13 SC during the pandemic, while eight patients switched from CT-P13 IV to CT-P13 SC to help alleviate the healthcare resource burden and minimize the risks inherent to multiple hospital visits for IV infusions. As such, this case series shares valuable clinical experience with CT-P13 SC in PsA and provides a unique insight into CT-P13 SC therapy during the COVID-19 pandemic.

2 | CASE PRESENTATIONS

Patients 1–3 were treated at Rheumazentrum Ruhrgebiet, Herne, Germany, and Patients 4–10 at the Royal Wolverhampton Hospitals NHS Trust, Wolverhampton, UK (Table 1). Patients 1 and 2 had an indication for changing immunomodulatory therapy; therapy was initiated with CT-P13, with SC administration preferred because of the COVID-19 pandemic. Patients 3–10 were receiving CT-P13 for the treatment of PsA and agreed to switch from CT-P13 IV to CT-P13 SC to help alleviate the healthcare resource burden and minimize the risks inherent to multiple hospital visits for IV infusions. As such, this case series shares valuable clinical experience with CT-P13 SC in PsA and provides a unique insight into CT-P13 SC therapy during the COVID-19 pandemic.

2.1 | Patients initiating and continuing CT-P13 SC treatment

Two patients in this case series initiated infliximab treatment with CT-P13 SC and were continuing CT-P13 SC treatment at last follow-up.

Patient 1 was diagnosed with PsA with axial involvement in 2012 (Table 1). Prior to initiating CT-P13 SC, the patient had highly active psoriasis (PsO) alongside pain and arthralgia in several joints, with the right knee requiring corticosteroid infiltration due to joint effusion, minor generalized synovitis, and a hypertrophic synovial nodule. On laboratory testing, the patient had elevated inflammatory markers. The patient initiated CT-P13 in September 2020 with two 5 mg/kg IV inductions, after which treatment continued with CT-P13 SC. Treatment was paused for 4 weeks from late October 2020, following a positive severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) polymerase chain reaction (PCR) test and resumed following resolution of infection symptoms. At follow-up (January 2021), examination found improvements in skin PsO and joint symptoms, with normalization of blood parameters.

Patient 2 was initially diagnosed with PsA in March 2017 (Table 1). Prior to initiating CT-P13 SC, the patient reported pain at multiple sites with swelling of the right metacarpophalangeal joint III, and pronounced achillodynia and bursitis subachillae requiring cortisone infiltration of the left ankle. She had BSA involvement of 45% with nail PsO of all fingernails. The patient initiated CT-P13 with two 5 mg/kg IV inductions in July 2020 and continued therapy with CT-P13 SC. At follow-up (January 2021), improvements in both joint and skin symptoms were noted.

For both patients, adherence to CT-P13 SC treatment was high, and CT-P13 SC was well tolerated with no side effects, as determined by a patient questionnaire.

2.2 | Patients who switched from CT-P13 IV to CT-P13 SC and continued CT-P13 SC treatment

Five patients in this case series switched from existing CT-P13 IV treatment to CT-P13 SC and were continuing treatment with CT-P13 SC at their last follow-up.

Patient 3 was diagnosed with PsA in June 2019 (Table 1); he had no other medical history nor family history of PsA. Before initiating CT-P13 IV treatment, the patient had
### Table 1  Patient demographics, treatment history and disease activity

| Patient # | Sex | Age, years | Body weight, kg | Year of PsA diagnosis | Prior treatment | CT-P13 treatment | Disease activity | At follow-up | Safety |
|-----------|-----|------------|----------------|-----------------------|----------------|------------------|------------------|-------------|--------|
| 1         | Male| 40         | 92             | 2012                  | MTX            | Initiated infliximab with CT-P13 SC | BSA: 24%; clear scalp psoriasiform plaques on head, ears, hands, elbows, knee joints, groin, and gluteal area, and nail PsO of fingernails | BSA: 10%; improved skin PsO on head, elbows, and knees | No side effects reported by patient |
|           |     |            |                |                       |                | Continuing CT-P13 SC at last follow-up | Pain in cervical spine and thoracolumbar area, radiating into gluteal area and groin | CRP: 0.2 mg/dl ESR: 7 mm/h |        |
|           |     |            |                |                       |                | Arthralgia in hands, fingers, and knees; right knee joint effusion, minor generalized synovitis, and hypertrophic synovialitic nodule (lateral parapatellar) requiring corticosteroid infiltration | Fist closing possible, with painful pressure at MCP joints II to V and PIP joints III and V (right hand) and MCP joints II to III (left hand) | CRP: 2.1 mg/dl ESR: 36 mm/h |        |
|           |     |            |                |                       |                |                  | Uric acid: 9.5 mg/dl |             |        |
| Patient # | Sex   | Age, years | Body weight, kg | Year of PsA diagnosis | Prior treatment | CT-P13 treatment | Disease activity | At follow-up | Safety |
|-----------|-------|------------|-----------------|-----------------------|----------------|------------------|-----------------|-------------|--------|
| 2         | Female| 53         | 94              | 2017                  | Sulfasalazine, Etanercept, Ustekinumab | Initiated infliximab with CT-P13 SC | BSA: 45%; PsO plaques on hands, ears, groin, and lower legs, with nail PsO of all fingernails | BSA: <10%; regressive PsO plaques on the hands, ears, and groin | No side effects reported by patient |
| 3         | Male  | 64         | 82              | 2019                  | Leflunomide, CT-P13 IV | Switched from CT-P13 IV to CT-P13 SC | BSA: 5%, with medium-sized scaly skin lesions of both elbows and sporadically over the thighs | BSA: 0% | Slight reddening at the injection site (first 2 SC administrations) |
| Patient # | Sex  | Age, years | Body weight, kg | Year of PsA diagnosis | Prior treatment | CT-P13 treatment | Disease activity | At follow-up | Safety |
|-----------|------|------------|-----------------|-----------------------|----------------|-----------------|-----------------|-------------|--------|
| 4         | Male | 40         | 85              | 2003                  | MTX Infliximab IV CT-P13 IV | Switched from CT-P13 IV to CT-P13 SC Continuing CT-P13 SC at last follow-up | DAS28: 0.77 VAS pain: 20 CRP: <0.1 mg/dL | Improvement in symptoms CRP: 0.02 mg/dL | No side effects reported by patient |
| 5         | Female | 26            | 65              | 2016                  | Hydroxychloroquine MTX CT-P13 IV +MTX | Switched from CT-P13 IV to CT-P13 SC Continuing CT-P13 SC at last follow-up | DAS28: 3.15 VAS pain: 30 TJC: 3/28 (9/78 prior to CT-P13 IV initiation) SJC: 2/28 (14/76 prior to CT-P13 IV initiation) CRP: <0.1 mg/dl ESR: 7 mm/h Prior to initiation of CT-P13 IV, patient's VAS was 3/5 and physicians' VAS was 3/5 | No disease flares CRP: <0.02 mg/dl | No side effects reported by patient |
| 6         | Female | 36            | 85              | 2014                  | Leflunomide CT-P13 IV +MTX | Switched from CT-P13 IV to CT-P13 SC Continuing CT-P13 SC at last follow-up | Physician's global VAS: 1/5 Patient's global VAS: 1/5 | Patient's global VAS: 1/5 CRP: 0.1 or 0.2 mg/dl | No side effects reported by patient |
| Patient # | Sex   | Age, years | Body weight, kg | Year of PsA diagnosis | Prior treatment | CT-P13 treatment | Disease activity | At follow-up | Safety |
|-----------|-------|------------|-----------------|-----------------------|----------------|------------------|-----------------|-------------|--------|
| 7         | Male  | 57         | 104             | 2017                  | Infliximab IV  | Switched from CT-P13 IV to CT-P13 SC | Physician's global VAS: 1/5 | CRP: 0.3 mg/dL | No side effects reported by patient |
|           |       |            |                 |                       | CT-P13 IV      | to CT-P13 SC at last follow-up | Patient's global VAS: 0/5 |            |        |
| 8         | Female| 57         | 81              | 2008                  | Adalimumab     | Switched from CT-P13 IV to CT-P13 SC | DAS28: 2.74 | CRP: 0.2 mg/dL | Mild bruising post-injection |
|           |       |            |                 |                       | Infliximab IV  | to CT-P13 SC | VAS pain: 35 |            | No serious adverse events reported by patient |
|           |       |            |                 |                       | IV + MTX + leflunomide | Switched back to CT-P13 IV | CRP: 0.4 mg/dL |            |        |
| 9         | Male  | 45         | 101             | Prior to 2003         | MTX Infliximab IV | Switched from CT-P13 IV to CT-P13 SC | Physician's global VAS: 2/5 | Physician's global VAS: 3/5 | Needle phobia developed |
|           |       |            |                 |                       | CT-P13 IV      | to CT-P13 SC | Patient's global VAS: 2/5 | Patient's global VAS: 4/5 | No serious adverse events reported by patient |
| 10        | Male  | 78         | 79              | Prior to 2003         | Infliximab IV  | Switched from CT-P13 IV to CT-P13 SC | DAS28: 3.62 | CRP: 0.1 mg/dL | No serious adverse events reported by patient |
|           |       |            |                 |                       | CT-P13 IV      | to CT-P13 SC | VAS pain: 50 |            |        |

Note: Normal range cut-offs for laboratory parameters were: creatinine, 0.7–1.2 mg/dL; CRP, 0.5 mg/dL; ESR, 20 mm/h; uric acid, 7.0 mg/dL.
Abbreviations: BSA, body surface area; CRP, C-reactive protein; DAS28, Disease Activity Score in 28 joints; ESR, erythrocyte sedimentation rate; IV, intravenous; MCP, metacarpophalangeal; MTP, metatarsophalangeal; MTX, methotrexate; PIP, proximal interphalangeal; PsA, psoriatic arthritis; PsO, psoriasis; Q2W, every 2 weeks; SC, subcutaneous; SJC, swollen joint count; TJC, tender joint count; VAS, Visual Analog Scale.
arthralgia of both hands and fingers with joint swelling and dactylitis in the left hand, pressure pain in the left foot, and BSA involvement of 5%. Inflammatory markers and retention parameters were elevated. Due to possible renal insufficiency, therapy with other conventional synthetic disease-modifying antirheumatic drugs was deemed problematic and the patient initiated infliximab treatment with CT-P13 IV. He received approximately 1 year of CT-P13 IV treatment, before switching from CT-P13 IV to CT-P13 SC because of the COVID-19 pandemic. At follow-up (January 2021), the patient reported no arthralgia and no pain upon pressure in peripheral joints. There were no synovitic swellings, and skin PsO was absent. As determined by a patient questionnaire, adherence to CT-P13 treatment was high and tolerability was very good.

Patient 4 was diagnosed with PsO and PsA in 2003 (Table 1); he was seronegative for rheumatoid factor (RF) and anti-cyclic citrullinated peptide (anti-CCP) at presentation. In 2007, fused cervical vertebrae were identified on imaging, and he was diagnosed with ankylosing spondylitis; he had also undergone bilateral total hip replacement. There were no synovitic swellings, and skin PsO was absent. As determined by a patient questionnaire, adherence to CT-P13 treatment was high and tolerability was very good.

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trips to the hospital for IV infusions previously made her feel quite tired. Patient 6 reported that CT-P13 SC treatment was easier to fit around his life, and Patient 7 noted that CT-P13 SC treatment saved time. Patients 4–7 completed the SIAQ at the end of the follow-up period, while remaining on CT-P13 SC treatment. Mean scores were at least 7.25 for all domains other than feelings about self-injection, which was slightly lower at 6.25 (Table 3). All four of the patients gave the most positive score (10) for self-confidence and ease of use of the self-injection device.

2.3 | Patients who switched from CT-P13 IV to CT-P13 SC and decided to switch back to CT-P13 IV

Three patients in this case series switched from ongoing CT-P13 IV treatment to CT-P13 SC and later decided to switch back to CT-P13 IV.

Patient 8 was diagnosed with PsA in 2008 (Table 1), at which time she was seronegative for RF and anti-CCP and had psoriatic involvement of the skin, lower back, and peripheral joints, with significant hand deformities. The patient started treatment with adalimumab but difficulty with self-administration prompted her to switch to infliximab. Before switching, her PsARC score comprised a patient’s and physician’s VAS of 4 out of 5, with a TJC of 30 out of 78, and SJC of 18 out of 76. She received approximately 2 years of reference infliximab and 4 years of CT-P13 IV, both with concomitant MTX and leflunomide. After reference infliximab treatment, her PsARC score comprised a patient’s VAS of 4 out of 5 and a physician’s VAS of 3 out of 5, with a TJC of 4 out of 78, and an SJC of 3 out of 76. The patient was prescribed CT-P13 SC in April 2020 but due to a pandemic-related delay, treatment did not start until July 2020. Routine monitoring showed that her CRP levels remained consistent while receiving CT-P13 SC. In August 2020, the patient reported that CT-P13 SC treatment was not working as well as her prior therapy and switched back to CT-P13 IV.

Patient 9 was diagnosed with PsA prior to 2003 (Table 1). Before initiating infliximab treatment, the patient had psoriatic skin involvement. He went on to receive approximately 10 years of reference infliximab and 4 years of CT-P13 IV, and switched to CT-P13 SC because of the COVID-19 pandemic. Prior to switching, the physician’s and patient’s global VAS were both 2 out of 5. A delay in starting CT-P13 SC in June 2020 led to a flare in disease activity, and after 6 weeks of CT-P13 SC therapy, the patient developed a needle phobia. CRP level was maintained while receiving CT-P13 SC but following CT-P13 SC treatment, the physician’s and patient’s global VAS were 3 out of 5 and 4 out of 5, respectively. He reported that CT-P13 SC was not working as well as his prior therapy, and he also felt that CT-P13 IV was not as effective as his prior therapy with reference infliximab. The patient resumed CT-P13 IV treatment in August 2020.

Patient 10 was diagnosed with PsA prior to 2003 (Table 1) and had psoriatic skin involvement at presentation. He initiated infliximab treatment in 2007, receiving 9 years of reference infliximab and 4 years of CT-P13 IV. Because of the COVID-19 pandemic, the patient switched to CT-P13 SC. Prior to switching (in May 2020), his disease activity score in 28 joints was 3.62 and the VAS for pain was 50 (March 2020). CRP levels were stable while receiving CT-P13 SC; the most recent value (January 2021) was <0.02 mg/dL. He reported that the beneficial effect of CT-P13 IV wore off prior to the next dose but felt that the problem-free duration was longer with CT-P13 IV compared with CT-P13 SC treatment due to the dose schedule. He switched back to CT-P13 IV in July 2020.

No serious adverse events were reported by these three patients, although Patient 8 experienced mild bruising post-injection. The patient was not receiving anticoagulants. In light of the pandemic, follow-up was conducted by telephone and minimal clinical assessments were carried out; however, in general, clinical effectiveness parameters were maintained. The patients completed the SIAQ at the end of the follow-up period, after they had switched back to CT-P13 IV. Mean scores were lowest for the self-image domain, with the highest score, corresponding to the best experience, reported for the pain and skin reactions during or after injection domain (Table 3).

3 | DISCUSSION AND CONCLUSIONS

In this case series, consistently positive clinical outcomes were observed after patients initiated CT-P13 SC or switched from CT-P13 IV to CT-P13 SC. Of 10 patients, seven were continuing CT-P13 SC at last follow-up for reasons including increased convenience. Three patients decided to switch back to CT-P13 IV: In each case, the patient reported that CT-P13 SC treatment was not as effective as CT-P13 IV, although two of the patients had not been satisfied with the effectiveness of their previous CT-P13 IV treatment. CRP levels were maintained for the three patients. Since the decision to persist with CT-P13 SC treatment was not based on objective findings such as CRP level, this suggests that other factors may have driven patient’s choices to switch back to CT-P13 IV, including subjective perceptions of reduced efficacy due to the nocebo effect. SIAQ scores were not available for all patients who were continuing CT-P13 SC treatment at the end of follow-up, but in general, mean scores were higher for patients continuing CT-P13 SC compared with those
## TABLE 3
Mean SIAQ domain scores for Patients 4–10

| Patient # | Feelings about self-injection | Self-confidence | Self-image | Satisfaction with self-injection | Pain and skin reactions during or after injection | Ease of use of the self-injection device |
|-----------|-------------------------------|-----------------|------------|----------------------------------|-----------------------------------------------|----------------------------------------|
|           |                               |                 |            |                                  |                                               |                                        |
| Patients who decided to continue CT-P13 SC |                               |                 |            |                                  |                                               |                                        |
| 4         | 10                            | 10              | 10         | 9                                | 7                                             | 10                                     |
| 5         | 5                             | 10              | 10         | 6                                | 10                                            | 10                                     |
| 6         | 5                             | 10              | 10         | 10                               | 6                                             | 10                                     |
| 7         | 5                             | 10              | 9          | 10                               | 6                                             | 10                                     |
| Mean (SD) | 6.25 (2.17)                   | 10.00 (0.00)    | 9.75 (0.43)| 8.75 (1.64)                      | 7.25 (1.64)                                   | 10.00 (0.00)                           |
| Patients who decided to switch back to CT-P13 IV |                               |                 |            |                                  |                                               |                                        |
| 8         | 5                             | 4               | 3          | 5                                | 8                                             | 5                                      |
| 9         | 9                             | 8               | 5          | 10                               | 9                                             | 10                                     |
| 10        | 8                             | 5               | 6          | 7                                | 8                                             | 3                                      |
| Mean (SD) | 7.33 (1.70)                   | 5.67 (1.70)     | 4.67 (1.25)| 7.33 (2.05)                      | 8.33 (0.47)                                   | 6.00 (2.94)                            |

Abbreviations: IV, intravenous; SC, subcutaneous; SD, standard deviation; SIAQ, Self-Injection Assessment Questionnaire.

*Scored on a 10-point scale from 0 (worst experience) to 10 (best experience).
who decided to switch back to CT-P13 IV, particularly for self-confidence, self-image, and ease of use of the injection device domains. This suggests that patients who switched back to CT-P13 IV may have had less positive experiences; however, comparisons must be cognizant of low patient numbers and potential recall bias given questionnaires were completed at the end of follow-up.

Despite rheumatology guidelines advocating the move to SC administration of medications if possible during the pandemic,20 this is not welcomed by all patients. A single-center study conducted in patients with rheumatoid arthritis reported that many of those receiving IV-administered abatacept or tocilizumab prior to the COVID-19 pandemic did not agree to switch to the SC formulation when offered because of the pandemic situation.21 Among those who did agree to switch, the majority wished to return to IV formulations, citing reasons including worsening symptoms and a desire for regular face-to-face visits with healthcare providers.23 Taken together with our findings, these studies highlight the importance of offering patients a choice, while demonstrating that experiences with one biologic may not be transferable to others. Although the number of patients included in this case series is relatively low, our data suggest that patients receiving CT-P13 IV should be offered the opportunity to switch to CT-P13 SC, and that negative experiences with switching from IV to SC formulations of other biologics should not necessarily influence treatment approaches for CT-P13 SC.

In this case series, there were no new or unexpected safety findings for CT-P13 SC. Two patients reported adverse events during CT-P13 SC treatment: one case of slight reddening at the injection site and one case of bruising post-injection. The injection-site reactions reported herein were mild. In addition, one patient had a mild, symptomatic, and PCR-confirmed SARS-CoV-2 infection. CT-P13 SC treatment was interrupted for 4 weeks until symptom resolution, consistent with EULAR recommendations to consider changes to DMARD therapy on a case-by-case basis for patients with mild symptoms.24

The conclusions drawn reflect our experience with 10 patients treated at two centers in the UK and Germany. While relatively few patients were included in the case series, the patients were treated as part of routine clinical practice and are representative of the general PsA patient population. Our findings are limited by the observational nature of case reports, meaning that effectiveness and laboratory parameters were not collected beyond clinical requirements and thus, not consistently measured between cases. The pandemic context resulted in a reduction in face-to-face appointments and blood monitoring, with most consultations performed remotely, posing additional challenges to data collection in this real-world setting. However, this is the first report describing CT-P13 SC treatment in patients with PsA, thus providing valuable insights for rheumatologists and other stakeholders involved in treating the condition. While the case series was conducted during the COVID-19 pandemic, we believe that our observations of patients wishing to maintain CT-P13 SC treatment, rather than switch to IV-administered therapy, could be generalizable to the non-pandemic setting, particularly owing to the increased convenience of CT-P13 SC therapy for patients of working age. However, data collection in larger patient populations would be beneficial to further examine patient preferences.

In summary, our case series demonstrates that CT-P13 SC could provide effective, safe, and convenient treatment for patients with PsA, both in the context of the COVID-19 pandemic and beyond.

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CONFLICT OF INTEREST

Xenofon Baraliakos has received honoraria, grants, and participated in advisory boards for AbbVie, Amgen, Bristol Myers Squibb, Chugai, Galapagos, Gilead, Lilly, MSD, Novartis, Pfizer, Roche, Sandoz, and UCB. Haewon Jung is an employee of Celltrion Healthcare Co., Ltd. Nick Barkham has received honoraria and speakers fees from Celltrion. Styliani Tsiami and Sooraj Vijayan have no potential conflicts of interest to declare.

AUTHOR CONTRIBUTIONS

Xenofon Baraliakos contributed to analysis and interpretation of data, and drafted and critically revised the article. Styliani Tsiami collected data, contributed to analysis and interpretation, and drafted and critically revised the article. Sooraj Vijayan collected data, and drafted and critically revised the article. Haewon Jung contributed to analysis and interpretation of data, and drafted and critically revised the article. Nick Barkham collected data, contributed to analysis and interpretation, and drafted and critically revised the article. All authors take responsibility for the integrity of the work as a whole, and have given their approval for this version to be published.
ETHICAL APPROVAL
Patients 1–3 provided signed informed consent prior to changing therapy and for the use of their data for scientific projects, analysis, and communication. For Patients 4–10, the treatment described in this case series was a service development due to the COVID-19 pandemic and in response to NICE guidance, which is mandatory in the UK. Since the treatment was not part of a clinical trial, formal ethical submission was not required. All patients had a telephone call with their consultant to discuss the potential risks and benefits prior to the change of treatment and all agreed to it; approval was given by the NHS Trust (treatment provider) and the Clinical Commissioning Group (payer authority). Patients 4–10 provided written informed consent for their cases to be included in this article.

CONSENT
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DATA AVAILABILITY STATEMENT
All data generated or analyzed during this study are included in this published article.

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