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RESEARCH ARTICLE

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Long-term real-world evidence of SB5 (adalimumab biosimilar) treatment in patients with moderate-to-severe psoriasis from the British Association of Dermatologists Biologic and Immunomodulators Register (BADBIR)

Giampiero Girolomoni[a], Steven R. Feldman[b], Alexander Egeberg[c,d], Luis Puig[e], Jinah Jung[f], Hojung Jung[f] and Younju Lee[f]

[a]Section of Dermatology, Department of Medicine, University of Verona, Verona, Italy; [b]Department of Dermatology, Center for Dermatology Research, Wake Forest University School of Medicine, Winston-Salem, NC, USA; [c]Department of Dermatology, Bispebjerg and Frederiksberg Hospital, University of Copenhagen, Copenhagen, Denmark; [d]Department of Clinical Medicine, Faculty of Health and Medical Sciences, University of Copenhagen, Copenhagen, Denmark; [e]Department of Dermatology, IIB Sant Pau, Hospital de la Santa Creu i Sant Pau, Universitat Autònoma de Barcelona, Barcelona, Spain; [f]Samsung Bioepis, Incheon, Republic of Korea

ABSTRACT

Background: SB5 (adalimumab-bwwd) is an adalimumab biosimilar targeting tumor necrosis factor (TNF) for the treatment of chronic inflammatory diseases, including moderate-to-severe chronic plaque psoriasis.
Objectives: To assess the four-year persistence associated with the effectiveness and safety of SB5 in patients with psoriasis in the UK and Ireland.
Methods: This prospective study included 1195 SB5-treated patients using British Association of Dermatologists' Biologic Interventions Register (BADBIR) between 01 June 2018 and 31 August 2022. Persistence was defined as the time from biologic therapy initiation to discontinuation and Kaplan-Meier analysis was used to evaluate SB5 discontinuation rates. Cox regression was used to investigate the effect of covariates on the time-to-first-discontinuation of SB5 with the potential covariates.
Results: SB5 one-, two-, three-, and four-year discontinuation rates were 26.5%, 37.2%, 41.9%, and 43.3%, respectively. Tested covariates such as switching, age, sex, body mass index (BMI), and duration of psoriasis did not significantly affect the discontinuation rate of SB5.
Conclusions: Median persistence of SB5 in predominantly bio-naïve psoriasis patients was about 2.5 years in clinical practice. The results suggest that SB5 can be confidently used for patients with psoriasis, offering comparable outcomes to reference adalimumab.

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KEYWORDS
Adalimumab; BADBIR; drug survival; psoriasis; real-world data; real-world evidence; registry; SB5

Introduction

Psoriasis is an immune-mediated chronic inflammatory disease affecting the skin, joints, and other organ systems with a prevalence of over 60 million patients across all age groups worldwide (1). Psoriasis requires long-term treatment, affecting patients' quality of life and posing a substantial social and economic burden (1). Biologic agents targeting TNF including adalimumab (2), etanercept (3), infliximab (4), and certolizumab (5) have greatly improved treatment outcomes. According to the National Institute for Health and Care Excellence (NICE) guidance, adalimumab is recommended for the treatment of adult patients with moderate-to-severe chronic plaque psoriasis. Currently, adalimumab is among the most commonly prescribed biologic drugs for psoriasis worldwide, including in the United Kingdom (UK), the United States (US), and the European Union (EU) (6–9). However, despite its effectiveness, patient access to adalimumab is limited due to its high cost (10,11).

SB5 (adalimumab-bwwd, Hadlima™ in the US and Imraldi™ in the EU, Samsung Bioepis, Republic of Korea), an approved adalimumab biosimilar, is a fully humanized monoclonal antibody that specifically binds to TNF and blocks its interaction with the p55 and p75 cell surface TNF receptors, hence neutralizing its biological functions (12,13). SB5 is indicated for the treatment of various inflammatory diseases, including but not limited to moderate-to-severe chronic plaque psoriasis, psoriatic arthritis (PsA), hidradenitis suppurativa, rheumatoid arthritis (RA), and inflammatory bowel disease (14).

Herein, we report a four-year follow-up study of an adalimumab biosimilar in over 1000 patients with psoriasis using a real-world psoriasis registry. Use of biologics in psoriasis, although it yields positive therapeutic results, is not without numerous side effects. In some cases, these complications are connected to the discontinuation of therapy (15). Thus, the objective of this observational real-world study was to evaluate the long-term drug persistence of SB5 in patients with psoriasis as a proxy for its effectiveness, safety and tolerability.

Methods

Data source

The British Association of Dermatologists' Biologic Interventions Register (BADBIR) is a multicenter prospective observational cohort established in 2007 to evaluate the long-term effectiveness and

CONTACT Giampiero Girolomoni giampiero.girolomoni@univr.it Piazzale Ludovico Antonio Scuro 10 - 37124 Verona, Italy

safety of biologics and conventional systemic therapies in adult patients with psoriasis in the UK and Ireland, and has recruited over 21,000 patients (16). Details on the BADBIR study design and its follow-ups have been described previously (17).

Study design and study population

Eligible patients were those registered in BADBIR with mild (baseline absolute Psoriasis Area and Severity Index (PASI) or Dermatology Life Quality Index (DLQI) <10) or moderate-to-severe psoriasis (baseline absolute PASI and DLQI ≥ 10) and treated with SB5 between 01 June 2018 and the database lock on 31 August 2022. Data from eligible patients were collected and analyzed to assess the drug persistence of SB5 including baseline demographics and disease characteristics, change in therapy, and drug discontinuation. Baseline absolute PASI and DLQI were assessed upon enrollment or at the start of SB5 treatment. Drug discontinuation rate was estimated by Kaplan-Meier analysis.

Statistical analysis

All analyses were performed with SAS statistical software version 9.4 (SAS Institute Inc., Cary, NC, US). Baseline characteristics were reported as either mean with standard deviation (SD) or median with the minimum (min) and maximum (max) for continuous variables. Categorical variables were reported as frequencies with percentages.

Survival analysis was used to evaluate the SB5 discontinuation rate over time, which defined SB5 discontinuation as the event of interest. Patients who continued SB5 treatment were censored until the cutoff date (31 August 2022). If patients had multiple discontinuations, only the time until the first discontinuation event was used for the survival analysis. Kaplan-Meier estimation was used to estimate the 95% confidence interval (CI) for the discontinuation rate. Median persistence time and the corresponding 95% CI were also estimated. Discontinuation rates at one year, two years, three years, and four years, along with the corresponding 95% CIs, were calculated. Based on the Kaplan-Meier estimation results, a survival plot for the persistence rate of SB5 was generated.

Cox regression was used to investigate the effect of covariates on the time-to-first-discontinuation of SB5, considering the potential covariates including age, sex, race, BMI, presence of PsA, number of comorbidities, duration of psoriasis, subtype of psoriasis, baseline PASI score, baseline DLQI, concomitant methotrexate use, previous biologic therapy, and occurrence of switching from reference to SB5.

Table 1. Baseline characteristics of SB5-treated patients.

Characteristics	N = 1195
Age (years)	45.7 ± 13.32
Gender, male	750 (62.8%)
Race, Caucasian	302 (25.3%)
BMI (kg/m^2, n = 274)	31.8 ± 7.24
PASI at SB5 start (n = 515)	9.1 ± 8.32
DLQI at SB5 start (n = 312)	14.6 ± 8.59
Disease duration (years, n = 320)	22.3 ± 14.34
Baseline psoriasis, n (%)	317 (26.5%)
Guttate	28 (2.3%)
Scalp psoriasis	205 (17.2%)
Nail psoriasis	156 (13.1%)
Unstable	14 (1.2%)
PsA, n (%)	80 (6.7%)
Comorbidity	442 (37.0%)
High blood pressure	70 (5.9%)
Depression	76 (6.4%)
Asthma	31 (2.6%)
Diabetes	35 (2.9%)
Liver disease	30 (2.5%)
Others	200 (16.7%)
Previous biologic experience	23 (1.9%)
Switch from adalimumab to SB5	16 (1.3%)
Previous systemic therapy	310 (25.9%)
Methotrexate	249 (20.8%)
Ciclosporin	162 (13.6%)
Acitretin	120 (10.0%)
Other	95 (7.9%)
Previous UV therapy	189 (15.8%)
Concomitant with systemic therapy[a]	149 (12.5%)
Methotrexate	112 (9.4%)
Ciclosporin	17 (1.4%)
Acitretin	14 (1.2%)
Other	8 (0.7%)

Note: Continuous data are reported as mean ± standard deviation unless otherwise stated, and categorical data are presented as a percentage.
Abbreviations: BMI: body mass index; DLQI: Dermatology Life Quality Index; E: number of available events in each category (concomitant systemic therapy); Min: minimum; Max: maximum; N: total number of SB5-registered patients; n: number of available patients in each category; PASI: Psoriasis Area and Severity Index; PsA: psoriatic arthritis; SB5: adalimumab biosimilar.
[a]If stop date of systemic therapy was missing, the medication record was regarded as concomitant therapy.

Results

Baseline characteristics

1195 patients (445 [37.2%] female, 750 [62.8%] male) with psoriasis treated with SB5 between 01 June 2018 and 31 August 2022 were included in this study (Table 1). The mean age was 45.7 years and the mean body mass index (BMI) was 31.8 kg/m^2. 302 (25.3%) patients were Caucasian; 220 (18.4%) patients had smoking history; 753 (63.0%) patients had no comorbidities; 80 (6.7%) patients also had PsA with an average disease duration of 22.3 years; 23 (1.9%) had a previous treatment history with biologics; and 16 (1.3%) had switched from reference adalimumab to SB5 (Table 1). Among patients with baseline data available, mean baseline PASI (SD) at the start of SB5 treatment was 9.1 (8.50) (n = 515) and mean baseline DLQI (SD) was 14.6 (8.59) (n = 312).

Duration of treatment period

Overall, 1195 patients had a mean (SD) treatment duration of 25.2 months (14.12). Treatment periods that resulted in discontinuation (490/1195; 41.0%) lasted on average 11.2 months (8.39) (Table 2).

Drug persistence

Out of 1195 patients, the Kaplan-Meier estimates of SB5 discontinuation rates (% (95% CI)) were 26.5% (24.0, 29.0), 37.2% (34.4, 39.9), 41.9% (39.0, 44. 8), and 43.3% (40.2, 46.5) at one-, two-, three- and four-years, respectively (Figure 1, Table 3). In total, 490 of 1195

Table 2. Treatment period of SB5.

Category	Statistics	
Duration of treatment period (months)	n	1195
	Mean (SD)	25.2 ± 14.12
	Median (Min, Max)	29.7 (0.0, 47.5)
Duration of treatment period among SB5-discontinued patients (months)	n	490
	Mean (SD)	11.2 (8.39)
	Median (Min, Max)	9.0 (0.0, 42.1)

Abbreviations: Max: maximum; Min: minimum; N: total number of SB5-registered patients; n: number of patients with available measurement; SB5: adalimumab biosimilar; SD: standard deviation.

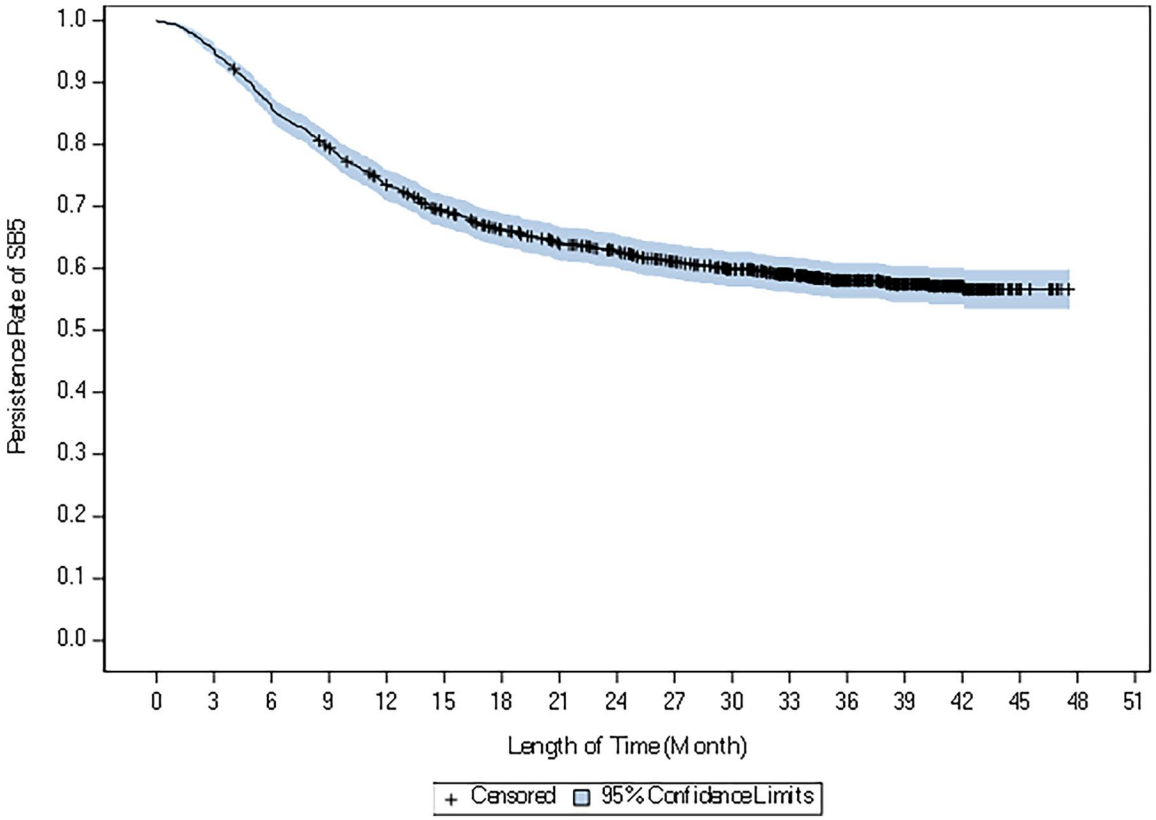

Figure 1. Drug persistence rate of SB5 treatment courses in patients with psoriasis in long-term follow-up. Kaplan–Meier curve illustrates the drug persistence rate of SB5 treatment courses over time. Treatment discontinuation is recorded as an event of interest. Only the time until the first discontinuation event was considered for patients who had multiple discontinuations. Abbreviation: SB5: adalimumab biosimilar.

Table 3. Analysis of SB5 discontinuation rate.[a]

SB5 study cohort (N = 1195)		
Number of patients censored	n/n′ (%)[b]	705/1195 (59.0)
Number of patients discontinued	n/n′ (%)[b]	490/1195 (41.0)
Discontinuation rate at one year[c]	% (95% CI)	26.5 (23.99, 28.99)
Discontinuation rate at two years[c]	% (95% CI)	37.2 (34.39, 39.91)
Discontinuation rate at three years[c]	% (95% CI)	41.9 (39.02, 44.78)
Discontinuation rate at four years[c]	% (95% CI)	43.3 (40.21, 46.46)

Abbreviations: %: percentage; CI: confidence interval; N: total number of SB5-registered patients; n: number of treatment courses in the stratified categories; n′: total number of treatment courses; SB5: adalimumab biosimilar.
[a]If patients experienced multiple discontinuations, only the time until the first discontinuation event was considered for the analysis.
[b]Percentages were calculated based on n′.
[c]Median discontinuation time of SB5, its 95% CI, and discontinuation rate at a specific timepoints are Kaplan–Meier estimates.

Table 4. Reasons for SB5 discontinuation.[a]

Reasons for discontinuation (N = 1195)	All Patients n/n′ (%)[b]
Any reason	490/1195 (41.0)
Inefficacy	159/1195 (13.3)
Adverse events	150/1195 (12.6)
Patient choice	77/1195 (6.4)
Inefficacy and adverse events[c]	29/1195 (2.4)
Contraindication	22/1195 (1.8)
Patient noncompliance	10/1195 (0.8)
Titration	8/1195 (0.7)
Death	6/1195 (0.5)
Financial consideration	1/1195 (0.1)
Remission	1/1195 (0.1)
Other	27/1195 (2.3)

Abbreviations: %: percentage; N: total number of SB5-registered patients; n: number of patients in stratified discontinuation reasons; n′: total number of patients in each group; SB5: adalimumab biosimilar.
[a]If patients experienced multiple discontinuations, only the time until the first discontinuation event was considered for the analysis.
[b]Percentages were calculated based on n′.
[c]Data are presented as per the BADBIR registry. There is no overlap between this reason for discontinuation and 'Inefficacy' and 'Adverse events' listed in this table.

SB5-treated patients (41.0%) discontinued SB5 (Table 4). Among them, 159 (13.3%) patients were reported to have discontinued due to inefficacy, and 150 (12.6%) discontinued due to adverse events (AEs). Death was reported in 6 patients (0.5%) and all of them were recorded as not related to SB5.

Predictors of SB5 persistence

None of the potential covariates (age, sex, race, BMI, presence of PsA, number of comorbidities, duration of psoriasis, subtype of psoriasis, baseline PASI score, baseline DLQI, concomitant methotrexate, previous biologic therapy, and switching) significantly affected the discontinuation rate of SB5, as all hazard ratio confidence intervals included 1 and p values were above 0.05 (Table 5).

Discussion

SB5 was approved as a adalimumab biosimilar based on the results of a pivotal phase 3 study comparing SB5 with reference

Table 5. Analysis of potential predictors[a] of drug survival from Cox regression model[b].

Risk factor	Hazard ratio (95% confidence interval)
Age	1.01 (0.99, 1.02)
Sex (male vs. female)	1.09 (0.70, 1.70)
Ethnicity (white vs. others)	0.63 (0.25, 1.58)
BMI	
25≤ <30	1.08 (0.51, 2.32)
30≤ <35	1.14 (0.52, 2.47)
35≤ <40	1.41 (0.60, 3.30)
≥40	1.90 (0.80, 4.53)
Psoriatic arthritis (yes vs. no)	0.81 (0.49, 1.37)
Number of comorbidities	
1–2	1.60 (0.88, 2.90)
>2	1.80 (0.95, 3.42)
Disease duration of psoriasis	0.99 (0.98, 1.01)
Psoriasis subtype at baseline	
Nails	0.87 (0.58, 1.32)
Palms	0.89 (0.46, 1.72)
Scalp	1.16 (0.74, 1.83)
Flexural	1.14 (0.72, 1.81)
Unstable	1.38 (0.51, 3.69)
PASI at baseline (<10 vs. ≥10)	0.98 (0.57, 1.68)
DLQI at baseline (<10 vs. ≥10)	1.15 (0.65, 2.02)
Concomitant methotrexate use (yes vs. no)	0.89 (0.45, 1.73)
Previous biologic therapy	
1	0.52 (0.12, 2.21)
2	2.83 (0.30, 26.78)
>2	0.00 (0.00, NC)
Switch from ADA to SB5 (yes vs. no)	1.44 (0.21, 10.03)

Abbreviations: NC: not calculated; ADA: reference adalimumab; BMI: body mass index; DLQI: Dermatology Life Quality Index; PASI: Psoriasis Area and Severity Index; SB5: adalimumab biosimilar.
[a]Potential predictors were selected based on literature review.
[b]Cox regression model was used to investigate the effect of covariates on the time-to-first-discontinuation of SB5.

adalimumab in the treatment of moderate-to-severe active RA (18–20). Furthermore, through the randomized, double-blind, parallel-group, active-controlled study in patients with plaque psoriasis, SB5 exhibited interchangeability to reference adalimumab (12,21). Another form of data, real-world evidence (RWE) studies, are of great importance for further confirming the effectiveness and safety of a product in the post-marketing phase (22). Especially, drug persistence is commonly used as a proxy measure of drug effectiveness, safety, and tolerability, reflecting how long patients continue using the medication (23,24). This study offers significant practical value by thoroughly investigating the long-term drug survival of an adalimumab biosimilar in over 1000 patients with psoriasis, encompassing a period of four years.

According to our results, 73.5% of psoriasis patients treated with SB5 remained on treatment after one year and 56.7% still receiving the drug after four years of treatment. The main reasons for drug discontinuation were inefficacy, AEs, and patient choice. The majority of discontinuations due to inefficacy or AEs occurred within one year, with a median time to discontinuation of 6.6 and 6.3 months, respectively. For some patients, the timing of treatment discontinuation roughly coincided with the onset of COVID-19 pandemic, suggesting that the pandemic may have influenced the discontinuation decision. However, no information related to COVID-19 was collected in the registry.

Drug persistence of adalimumab has been reported from various registries. In a study from the Biological Treatment in Danish Dermatology registry, the probability of drug survival for adalimumab was 77.4%, 65.5% and 54.9% at 26 weeks, 52 weeks and 104 weeks, respectively, when used as a first-line therapy (25,26). Real-world data from the Czech Republic's BIOREP registry reported drug persistence rates of 75.6% and 58.1% for adalimumab as a first-course biologic, and 66.7% and 50.1% for adalimumab as a second-course biologic, at 20 months and 80 months, respectively (27). Other prospective studies of BADBIR revealed overall adalimumab drug persistence rates of 79%, 67%, and 59% as first-course biologic (28), and 74%, 59%, and 50% as second-course biologic at one-, two-, and three-years, respectively (29). Thus, given that our data included mostly biologic-naïve (98.7%) patients, the results of our study, corresponding to persistence rates of 73.5% and 56.7% at one- and four-years, are generally consistent with previous findings of adalimumab in biologic-naïve patients.

In the BIOREP registry, female sex, obesity, baseline PASI score, and number of previous biologic therapies were associated with higher risk of discontinuation. On the other hand, a negative predictor of adalimumab persistence was the duration of psoriasis, which reduced the risk of discontinuation by 9% for every 10 years. A single center real-world study on more than 400 patients reported that the drug survival of adalimumab biosimilars at one year was 81.5% in the overall study population (30). Obesity was associated with increased risk of adalimumab discontinuation whereas PsA and receiving adalimumab as first systemic treatment were associated with lower risk. In our study, none of the potential covariates were associated with increased risk of SB5 discontinuation. Although not significant, risk of SB5 discontinuation was increased by hazard ratios of 1.08, 1.14, 1.41, 1.90 for BMI scores of 25–30, 30–35, 35–40, and ≥40. Obesity is a complex disease associated with an increase in several inflammatory markers, leading to chronic low-grade inflammation (31). Besides its direct impact on inflammation, obesity can also modify the pharmacokinetics (PK) of anti-TNF and other biologic agents. High body weight was identified as a significant covariate for increased drug clearance, resulting in a shorter half-life and lower serum trough drug concentrations in population PK modeling studies for anti-TNF biologics (32,33). Thus, the impact of obesity on PK may have partially contributed to a reduced clinical response to SB5, i.e., treatment discontinuation (34).

Non-medical switching can occur across different clinical settings. A mandatory switch from reference adalimumab to SB5 (162 patients) in patients with hospital-treated psoriasis from the Biological Treatment in Danish Dermatology (DERMBIO) cohort reported a one-year drug retention rate of 92.0%, which was comparable to the reference adalimumab cohort (92.1% in 32 patients) (35). In a Spanish multicenter study, the real-world drug persistence of adalimumab biosimilars was higher in patients with nonmedical switching than in patients who initiated an adalimumab biosimilar *de novo* (91.4% and 85.6% persistence rates at one- and two-year vs. 52.3% and 34.1% at one- and two-year, respectively) (36). Results from these two studies suggest that persistence of adalimumab biosimilars following non-medical switching is greater than 90% at one-year, whereas the persistence rates for bio-naïve patients in the Spanish study were lower than in our cohort (73.5% and 62.8% at one- and two-year, respectively) as a first-line therapy. Overall, discrepancies may be related to differences in treatment patterns including switching conditions, guidelines and efficacy expectations between countries, as well as varying accessibility to newer biologic drugs with better efficacy in real-world practice. Taken together, our current study broadly reflects and confirms the findings of experiences in other countries. The study further substantiates the long-term persistence of SB5 in treating psoriasis.

Limitations

In this study, we relied on registry data, which, while valuable, comes with certain inherent limitations. One significant constraint

is the lack of a control or comparison group, which makes it difficult to compare outcomes directly. Furthermore, the study population included patients registered in the UK and Ireland. Accordingly, appropriate caution should be taken when generalizing the results from this study to other populations, and different social settings on drug persistence such as familiarity and attitude toward biosimilars should be considered. Switching was not a predictor of drug discontinuation from the Cox regression model, but the small number of switching cases poses a limitation. Finally, effectiveness data were obtained from only a small number of patients, and thus there were limited data available on effectiveness outcomes in the real-world setting.

Conclusions

This RWE study assessed the long-term drug persistence rate of SB5 in predominantly bio-naïve patients with psoriasis followed for up to four years. Overall, median persistence of treatment with SB5 was about 2.5 years in clinical practice which is comparable to that of reference adalimumab. The results further support SB5 as an effective and safe treatment option for plaque psoriasis and other diseases for which innovator and adalimumab biosimilars are approved. The availability of biosimilars for the treatment of patients with moderate-to-severe psoriasis could facilitate patient access to effective therapies and reduce the substantial socio-economic burden of biologics.

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Ethics statement

BADBIR was approved in March 2007 by the National Health Service (NHS) Research Ethics Committee North-West England, reference 07/MRE08/9. All patients gave written informed consent for their participation in the registry. BADBIR has ethical approval to continue following participants until 31 July 2028.

Disclosure statement

Giampiero Girolomoni has received consulting fees or honoraria for lectures from AbbVie, Almirall, Amgen, Boehringer-Ingelheim, Bristol-Myers Squibb, Eli-Lilly, Leo Pharma, Merck Serono, Novartis, Pfizer, Pierre Fabre, Samsung Bioepis and Sanofi. Steven R. Feldman has received research grants, consulting fees or honoraria for lectures from AbbVie, Accordant, Almirall, Alvetech, Arcutis, Biocon, Bausch, Bristol-Myers Squibb, Boehringer Ingelheim, Dermavant, Eli Lilly, Forte, Helsinn, Incyte, Janssen, Leo Pharma, Novartis, Ortho Dermatology, Pfizer, Samsung Bioepis, Sanofi, Sun, Regeneron, UCB. Alexander Egeberg has received research funding from AbbVie, Almirall, Boehringer Ingelheim, Bristol-Myers Squibb, Eli Lilly, Janssen Pharmaceuticals, Novartis, Pfizer, the Danish National Psoriasis Foundation, the Kgl Hofbundtmager Aage Bang Foundation, and the Simon Spies Foundation, and honoraria as consultant and/or speaker from Amgen, AbbVie, Almirall, Boehringer Ingelheim, Bristol-Myers Squibb, Dermavant, Eli Lilly and Company, Galápagos NV, Galderma, Horizon Therapeutics, Janssen Pharmaceuticals, Leo Pharma, McNeil Consumer Healthcare, Mylan, Novartis, Pfizer, Samsung Bioepis Co., Ltd., Sun Pharmaceuticals, UCB, Union Therapeutics, and Zuellig Pharma Ltd. Luis Puig has received research grants, consulting fees or honoraria for lectures from AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly, Janssen, JS BIOCAD, Leo Pharma, Novartis, Pfizer, UCB, Samsung Bioepis, Sandoz. Hojung Jung, Jinah Jung, and Yonju Lee are employees of Samsung Bioepis. Detailed conflict of interest for each author are disclosed and provided per ICMJE form according to Journal requirements.

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ORCID

Steven R. Feldman http://orcid.org/0000-0002-0090-6289
Alexander Egeberg http://orcid.org/0000-0001-8257-1816
Jinah Jung http://orcid.org/0000-0003-2439-377X
Hojung Jung http://orcid.org/0009-0005-2660-2469

Data availability statement

The BADBIR Study Group comprises the BADBIR Steering Committee and the BADBIR Data Monitoring Committee (DCM). BADBIR Steering Committee members are: http://www.badbir.org/Clinicians/Information/SteeringCommittee. Members of the DMC are Prof Anja Strangfeld (Chair), Dr Girish Gupta, Imke Redeker and Dr Richard Weller. Restrictions apply to the availability of these data due to patient consent and licensing agreements; data were used under license for this study. The authors therefore cannot make these data publicly available.

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