Rheumatol Ther (2025) 12:469–492
https://doi.org/10.1007/s40744-025-00755-9

ORIGINAL RESEARCH

Real-World Experience with an Adalimumab Biosimilar (ABP 501) in Patients with Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis and Psoriasis in Europe: Results from the Adelphi Disease Specific Programme

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Received: November 6, 2024 / Accepted: February 19, 2025 / Published online: March 11, 2025

ABSTRACT

Introduction: Biosimilars have provided additional treatment options for patients with immune-mediated inflammatory diseases. This study evaluated the real-world use of adalimumab biosimilar ABP 501 in European patients with rheumatoid arthritis (RA), ankylosing spondylitis (AS), psoriatic arthritis (PsA), or psoriasis (PsO).

Methods: Data were drawn from the RA, spondyloarthritis, and PsO Adelphi Disease Specific Programmes (DSP)™, cross-sectional surveys conducted in France, Germany, Italy, Spain, and the UK between January 2020 and February 2022. Physicians completed patient record forms which collected data on demographics, treatment history, and clinical outcomes. Patients voluntarily completed questionnaires self-reporting health-related quality of life. Outcome measures were assessed for patients who initiated ABP 501 as the first advanced therapy (AT, "ABP 501 initiators") and patients who switched to ABP 501 from the first-line AT with reference product (RP) ("RP-ABP 501 switchers") in each indication.

Prior Publication: This is an original work and is not under consideration by any other journal. Data reported in this study were previously presented at the following conferences: American College of Rheumatology (ACR) Convergence 2022, November 10–14, 2022, Philadelphia, PA, USA: Jin R et al. Real-World Utilization of Adalimumab Biosimilar (ABP 501) in Patients with Rheumatoid Arthritis, Ankylosing Spondylitis and Psoriatic Arthritis in Europe. https://acrabstracts.org/abstract/real-world-utilization-of-adalimumab-biosimilar-abp-501-in-patients-with-rheumatoid-arthritis-ankylosing-spondylitis-and-psoriatic-arthritis-in-europe/; American Academy of Dermatology (AAD) Annual Meeting 2023, March 17–21, 2023, New Orleans, LA, USA: Jin R et al. Real-World Utilization of Adalimumab Biosimilar (ABP 501) in Patients with Psoriasis in Europe. https://eposters.aad.org/abstracts/42268.

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***Results*:** Across disease cohorts, 868 initiators and 428 switchers were analyzed. At time of consultation, physicians reported that 77.1%, 63.2%, 67.8%, and 83.0% of initiators with RA, AS, PsA, and PsO, respectively, presented with mild disease after receiving ABP 501 for a median of 10.4–12.3 months. Among switchers, the most common reasons for switching were related to formulary or financial reasons and insurance restrictions. Most switching patients were assessed by physicians to have mild disease (75.0–87.5% across indications) at time of consultation having received ABP 501 for a median of 11.2–15.3 months. Patients' self-assessment, including EQ-5D and work productivity scores, indicated an overall good state of health while using ABP 501, regardless of indication and prior RP exposure. Overall, more than 89% of physicians and more than 86% patients reported being satisfied with the disease control provided by ABP 501.

***Conclusion*:** Across indications, both physicians and patients reported positive clinical outcomes and high levels of satisfaction with ABP 501 treatment, regardless of prior use of RP.

Keywords: Adalimumab; Ankylosing spondylitis; Biosimilar; Patient-reported outcomes; Psoriasis; Psoriatic arthritis; Real-world; Rheumatoid arthritis; Physician survey; Treatment satisfaction

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Key Summary Points

Why carry out this study?

ABP 501 (Amgevita®) was the first biosimilar to the adalimumab reference product (Humira®) to be approved by the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA). It has been available for use since October 2018 in Europe and January 2023 in the USA.

Biosimilarity between ABP 501 and the adalimumab reference product has been demonstrated in two comparative clinical trials in patients with moderate to severe rheumatoid arthritis (RA) and patients with moderate to severe plaque psoriasis (PsO); however, barriers to utilization remain, especially for use in indications approved on the basis of extrapolation.

This study sought to understand real-world experience with biosimilar ABP 501 for treating RA, PsO, ankylosing spondylitis (AS), and psoriatic arthritis (PsA) from both physicians and patients regarding clinical efficacy, treatment pathway, treatment satisfaction, and patients' self-reported health-related quality of life.

What was learned from the study?

Across all studied indications (RA, AS, PsA, PsO), patients experienced positive treatment outcomes when receiving biosimilar ABP 501, and both physicians and patients reported being satisfied with the disease control provided by ABP 501 treatment, regardless of prior exposure to reference product.

These data add to the growing body of real-world evidence describing the positive physician and patient experience with biosimilar ABP 501 across a range of immune-mediated inflammatory diseases, providing useful context for physicians and their patients as the treatment landscape with biosimilars evolves.

INTRODUCTION

Rheumatoid arthritis (RA) [1], axial spondyloarthritis (axSpA), including ankylosing spondylitis (AS) [2, 3], psoriatic arthritis (PsA) [4], and psoriasis (PsO) [5] are immune-mediated inflammatory diseases (IMIDs) with a range of clinical manifestations involving the joints, bones, and skin [6–9]. Over the past decades, biological disease-modifying antirheumatic drugs (bDMARDs) such as tumor necrosis factor inhibitors (TNFi), amongst others, have revolutionized the treatment of these conditions. TNFis have been shown to improve signs and symptoms, slow down disease progression, and improve patients' daily functioning and health-related quality of life (HRQoL) [10–14].

In recent years, the advent of TNFi biosimilars, namely infliximab and adalimumab biosimilars, has provided alternative treatment options to patients with IMIDs. ABP 501 (AMGEVITA® [European Union; EU] or AMJEVITA® [USA], adalimumab-atto) was the first adalimumab biosimilar approved by the European Medicines Agency (EMA), becoming available for use in the EU in October 2018 [15]. It was also the first available adalimumab biosimilar in the USA (since January 2023), with an additional eight being approved and available on the market to date [16]. Biosimilarity of ABP 501 to its reference product (RP, HUMIRA®) with regard to efficacy, safety, and immunogenicity has been demonstrated in two randomized controlled, double-blinded, comparative clinical trials in patients with moderate to severe RA [17, 18] and patients with plaque PsO [19]. However, barriers to utilization remain. To date, there remains a paucity of real-world data (RWD) describing physicians' and patients' experience and utilization patterns of the biosimilar ABP 501. Provision of such RWD to the medical community and patients may help address potential barriers to utilization, especially in indications approved on the principle of extrapolation (such as in AS and PsA) where comparative clinical trial data are not available.

We previously presented data on patients with inflammatory bowel disease where we reported high satisfaction levels with ABP 501 treatment from both physicians and their consulting patients, alongside minimally impaired HRQoL as self-reported by patients [20]. In the current analysis, we aimed to understand physicians' perspectives in terms of clinical efficacy and treatment satisfaction, as well as to evaluate patients' self-assessment of their HRQoL while using ABP 501 for treating RA, AS, PsA, or PsO both as initiating (RP-naïve patients) or switching (patients switched to ABP 501 from RP) therapy.

METHODS

Data Source

Data were drawn from the RA, spondyloarthritis (SpA; collecting data from patients with AS or PsA), and PsO Adelphi Disease Specific Programmes (DSP)™ separately, conducted in France, Germany, Italy, Spain, and the UK between January 2020 and February 2022. DSPs are large, independent, cross-sectional surveys collecting both current and retrospective data from physicians and their consulting patients in a real-world clinical setting. The methodology has been previously described [21, 22], validated [23], and demonstrated to be representative and consistent over time [24].

Study Population

For each DSP survey wave, a geographically representative sample of physicians were recruited to participate. Physicians were eligible if they were personally responsible for and actively involved in treatment decisions and management of patients with RA, AS, PsA, or PsO. Rheumatologists needed to see at least eight patients with RA, five patients with AS or three patients with PsA in a typical month, and dermatologists needed to see at least six patients with PsA or ten patients with PsO per month to be eligible for inclusion.

Participating physicians were asked to complete a patient record form for their next 3–8 consecutively consulting patients with RA, AS, PsA, or PsO who visited their clinic for routine

care, regardless of prescribed medication(s), to mitigate against selection bias and to derive a patient sample representative of those currently consulting in a real-world clinical setting. Patients were eligible for inclusion if they were 18 years or older, had a physician-confirmed diagnosis of RA, AS, PsA, or PsO, visited the physician for routine care, and were not involved in a clinical trial at the time of consultation. With respect to patients with AS, no patients were previously prescribed ABP 501 or RP for their prior diagnosis of non-radiographic axial spondyloarthritis (if any) before inclusion in the survey.

In addition to those consecutively sampled patients, a deliberately collected additional set of patients for each studied indication who were receiving biosimilar ABP 501 (oversample) were recruited, in order to ensure a sufficient number of ABP 501 users for analysis. These oversamples followed the same methodology that was used for consecutively sampled patients, with patients fulfilling the same inclusion criteria.

Three treatment cohorts were included in the final analysis. Two ABP 501 cohorts comprised (1) patients who were receiving ABP 501 as the first advanced therapy (AT) at the time of consultation ("ABP 501 initiators") and (2) patients who were receiving ABP 501 following a direct switch from the first-line AT with adalimumab RP ("RP-ABP 501 switchers"). Direct switch for patients with RA, AS, and PsA was defined as transitioning from the RP-containing treatment regimen to a treatment regimen containing ABP 501 within 90 days, with no other AT in between. For patients in the PsO cohort, there were no data available for time to regimen switch; therefore, no stipulation was made with regard to the time between RP-containing treatment regimen and ABP 501 treatment, but patients received no other AT between RP and ABP 501. Additionally, a separate treatment cohort of patients who were receiving adalimumab RP as the first AT ("RP initiators") at the time of consultation was also drawn from the DSP sample as a reference cohort. All patients included in the analysis had initiated their current AT (either ABP 501 or RP) in or after October 2018 (first availability of ABP 501 in Europe).

Outcome Measures

Physician-Reported Assessment

Participating physicians reported patient data through abstraction of patient clinical records, supplemented by their knowledge of the patient and clinical judgement, consistent with decisions made in routine clinical practice. The patient record forms contained questions on patient demographics, disease diagnosis, treatment history, treatment satisfaction, and clinical outcomes at the time of consultation and at initiation of the ongoing treatment regimen. In addition to reporting the treatment received at time of consultation, physicians also provided the full treatment history retrospectively for each patient from the initial diagnosis (where historical data were available in patient clinical records), including the treatment start and end dates, allowing for duration of ongoing and previous treatment regimens to be calculated. The only exception was that treatment end date was not collected in the PsO DSP; thus, duration of treatment for patients with PsO was estimated from treatment start date to start date of the next regimen, making the assumption that there was no treatment gap in between.

Patient disease severity at initiation of current adalimumab treatment regimen and at the time of clinical consultation (while patients had been on adalimumab therapy) was assessed by their treating physicians and categorized into "mild", "moderate", or "severe" on the basis of physicians' current and historical knowledge of each individual patient and access to patient medical records. Level of pain for patients at the time of consultation was evaluated and reported by physicians as "none", "mild", "moderate", or "severe" categories in the RA and PsO DSPs, and using a numeric rating scale (ranging from 0 to 10, where 0 was none and 10 was the highest) in the SpA DSP which collected data for patients with AS or PsA. Across all indications, physicians were also asked to report their level of satisfaction with the treatment received at the time of consultation and select one or more

reasons for the treatment/regimen switch for the group of RP-ABP 501 switchers from a predefined list (options available related to efficacy, safety/tolerability, mode of action, mode of administration, COVID-19, access/cost, patient compliance, and patient request).

Patient-Reported Assessment

At the time of clinical consultation, these same patients were invited to voluntarily complete patient-reported questionnaires, reporting their level of satisfaction with current treatment and HRQoL measures, including the EQ-5D-5L index [25] and the Work Productivity and Activity Impairment (WPAI) questionnaire [26].

The EQ-5D-5L index [25] includes the EuroQoL visual analogue scale (EQ-VAS) and the EQ-5D-5L descriptive system of five domains. The EQ-VAS is a visual analogue scale ranging between 0 (worst imaginable health) and 100 (best imaginable health), on which patients provide a global assessment of their health. The EQ-5D-5L descriptive system assessed health-related QoL in terms of mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, where an overall health state index score ranging from 0 (indicating death) to 1 (indicating full health) was calculated on the basis of those five domains.

The WPAI questionnaire [26] measures specific disease-related time missed from work (absenteeism), impairment in effectiveness at work (presenteeism), overall work productivity loss (overall work impairment, i.e., absenteeism plus presenteeism), and non-work-related activity impairment (total activity impairment), with higher values indicating greater disease-related impairment. WPAI component scores are reported as percentage impairment, whereby 0% is no impairment and 100% is total loss of work productivity or activity.

Statistical Analysis

The current analysis was descriptive in nature. No a priori hypotheses were tested, and no statistical comparisons were conducted between groups. Summary statistics (e.g., mean and standard deviations [SD], or median and first quartile [Q1] and third quartile [Q3] for continuous variables; frequency and percentages for categorical variables) were reported for descriptive analyses of outcome measures. Missing data were not imputed; thus, sample sizes may vary between variables depending on availability of data. All analyses were performed using Stata v17.0 [27].

Ethical Approval

The data collection methodology and survey questionnaires were reviewed and approved by the Western Institutional Review Board (protocol numbers #1-1253914-1 [RA 2020 wave], #20210318 [SpA]) or Pearl Institutional Review Board (protocol numbers #21-ADRW-104 [RA 2021/2022 wave], #21-ADRW-124 [PsO]). Data collection was undertaken in line with European Pharmaceutical Marketing Research Association guidelines [28]; and the survey was performed in full accordance with relevant legislation at the time of data collection, including the US Health Insurance Portability and Accountability Act 1996 [29] and Health Information Technology for Economic and Clinical Health Act legislation [30], and in accordance with the principles stated in the Declaration of Helsinki. Using a checkbox, patients provided informed consent to take part in the survey, and for the use of their anonymized and aggregated data for research purposes.

RESULTS

Data from 1296 patients who were receiving ABP 501 (RA, $n=413$; AS, $n=194$; PsA, $n=418$; PsO, $n=271$) at the time of clinical consultation were included in this analysis. Of those, 868 (67.0%) patients were ABP 501 initiators and 428 patients (33.0%) were RP-ABP 501 switchers.

ABP 501 Initiators

Patient demographics and clinical characteristics of the ABP 501 initiators in each disease

Table 1 Physician-reported patient demographics, treatment history, and clinical characteristics for patients who initiated adalimumab product (ABP 501 or reference product (RP)) as the first advanced therapy

	Rheumatoid arthritis (RA)		Ankylosing spondylitis (AS)		Psoriatic arthritis (PsA)		Psoriasis (PsO)	
	ABP 501 initiators	RP initiators	ABP 501 initiators	RP initiators	ABP 501 initiators	RP initiators	ABP 501 initiators	RP initiators
Patient count, *n*	350	148	114	37	245	52	159	28
Demographics								
Age, mean (SD)	50.0 (12.8)	50.4 (11.0)	41.8 (12.3)	46.6 (12.9)	46.8 (11.0)	47.8 (12.7)	42.8 (11.9)	45.0 (9.7)
Sex, male, *n* (%)	122 (34.9)	65 (43.9)	100 (87.7)	27 (73.0)	126 (51.4)	29 (55.8)	85 (53.5)	17 (60.7)
Ethnicity, white, *n* (%)	316 (90.3)	146 (98.6)	114 (100.0)	36 (97.3)	219 (89.4)	47 (90.4)	150 (94.3)	23 (82.1)
Treatment patterns								
Time from diagnosis to first receipt of adalimumab product (ABP 501 or RP), months, median (IQR)[a]	21.7 (10.0, 38.3)	22.5 (8.4, 67.6)	21.5 (6.0, 56.9)	12.6 (7.9, 29.1)	17.2 (4.0, 42.5)	10.1 (3.0, 30.0)	40.1 (14.0, 95.4)	25.1 (10.0, 67.6)
Time duration on adalimumab product (ABP 501 or RP), months, median (IQR)	12.3 (7.4, 18.3)	8.5 (4.0, 13.5)	10.7 (5.1, 17.3)	13.9 (4.6, 17.8)	10.4 (4.8, 17.7)	13.1 (5.8, 19.4)	11.4 (5.1, 19.2)	13.8 (6.5, 20.8)

Table 1 continued

	Rheumatoid arthritis (RA)		Ankylosing spondylitis (AS)		Psoriatic arthritis (PsA)		Psoriasis (PsO)	
	ABP 501 initiators	**RP initiators**	**ABP 501 initiators**	**RP initiators**	**ABP 501 initiators**	**RP initiators**	**ABP 501 initiators**	**RP initiators**
Adalimumab monotherapy, *n* (%)	96 (27.4)	77 (52.0)	89 (78.1)	28 (75.7)	186 (75.9)	37 (71.2)	106 (66.7)	14 (50.0)
Adalimumab in combination with conventional therapy, *n* (%)								
Any combination	254 (72.6)	71 (48.0)	25 (21.9)	9 (24.3)	59 (24.1)	15 (28.8)	53 (33.3)	14 (50.0)
csDMARD	217 (62.0)	50 (33.8)	3 (2.6)	4 (10.8)	44 (18.0)	10 (19.2)	12 (7.5)	2 (7.1)
Steroids	32 (9.1)	11 (7.4)	1 (0.9)	5 (13.5)	11 (4.5)	2 (3.8)	30 (18.9)	9 (32.1)
Clinical status								
Disease severity at initiation of current adalimumab product, *n* (%)[b]								
Mild	30 (8.6)	13 (9.0)	8 (7.1)	1 (2.7)	20 (8.3)	3 (5.9)	4 (2.5)	1 (3.6)
Moderate	147 (42.2)	70 (48.3)	49 (43.4)	24 (64.9)	141 (58.5)	29 (56.9)	75 (47.2)	11 (39.3)
Severe	171 (49.1)	62 (42.8)	56 (49.6)	12 (32.4)	80 (33.2)	19 (37.3)	80 (50.3)	16 (57.1)
Disease severity at time of consultation, *n* (%)								
Mild	270 (77.1)	86 (58.1)	72 (63.2)	14 (37.8)	166 (67.8)	34 (65.4)	132 (83.0)	23 (82.1)
Moderate	63 (18.0)	52 (35.1)	36 (31.6)	21 (56.8)	68 (27.8)	17 (32.7)	21 (13.2)	2 (7.1)
Severe	17 (4.9)	10 (6.8)	6 (5.3)	2 (5.4)	11 (4.5)	1 (1.9)	6 (3.8)	3 (10.7)
Physician-reported patient pain, *n* (%)								
None	162 (46.3)	33 (22.3)	NA	NA	NA	NA	106 (66.7)	13 (46.4)
Mild	136 (38.9)	74 (50.0)					41 (25.8)	11 (39.3)
Moderate	42 (12.0)	33 (22.3)					9 (5.7)	3 (10.7)
Severe	10 (2.9)	8 (5.4)					3 (1.9)	1 (3.6)
Physician-reported patient pain, mean (SD)*	NA	NA	2.7 (2.3)	2.9 (2.3)	2.5 (2.1)	3.0 (1.9)	NA	NA

Table 1 continued

	Rheumatoid arthritis (RA)		Ankylosing spondylitis (AS)		Psoriatic arthritis (PsA)		Psoriasis (PsO)	
	ABP 501 initiators	**RP initiators**	**ABP 501 initiators**	**RP initiators**	**ABP 501 initiators**	**RP initiators**	**ABP 501 initiators**	**RP initiators**
Physician-reported satisfaction with current treatment, *n* (%)	314 (89.7)	121 (81.8)	111 (97.4)	37 (100.0)	234 (95.5)	51 (98.1)	151 (95.6)	24 (88.8)

ABP 501 initiators—patients who were receiving ABP 501 as their first advanced therapy at the time of consultation. RP initiators—patients who were receiving the reference product adalimumab as their first advanced therapy at the time of consultation

AS ankylosing spondylitis, *AT* advanced therapy, *csDMARD* conventional synthetic disease-modifying anti-rheumatic drug, *IQR* interquartile range, *NA* not applicable, *PsA* psoriatic arthritis, *PsO* psoriasis, *RA* rheumatoid arthritis, *RP* reference product, *SD* standard deviation

*Numerical scale rating, ranging from 0 to 10, where 0 represents no pain and 10 represents the highest level of pain

[a]RA $n = 298$, $n = 119$; AS $n = 106$, $n = 35$; PsA $n = 218$, $n = 47$; PsO $n = 111$, $n = 22$

[b]RA $n = 348$, $n = 145$; AS $n = 113$, $n = 37$; PsA $n = 241$, $n = 51$; PsO $n = 159$, $n = 28$

cohort are described in Table 1. Median time from disease diagnosis to initiation of ABP 501 as the first AT was 17.2 months in PsA, approximately 22 months in both RA and AS, and 40.1 months in PsO. Most ABP 501 initiators (AS, 78.1%; PsA, 75.9%; PsO, 66.7%) received ABP 501 as a monotherapy, while in patients with RA, 72.6% received ABP 501 as a combination therapy, mainly with a conventional synthetic disease-modifying anti-rheumatic drug (csDMARD; 62.0%) (Table 1). At the time of initiation of ABP 501 treatment, the proportion of patients with RA, AS, PsA, and PsO who were classified by their physician as having moderate or severe disease was 91.4%, 92.9%, 91.7%, and 97.5%, respectively. At the time of clinical consultation (patients having been on ABP 501 for a median of 10.4–12.3 months), physicians reported that 77.1%, 63.2%, 67.8%, and 83.0% of patients with RA, AS, PsA, and PsO, respectively, were presenting with mild disease. About 85% of patients with RA and over 90% of patients with PsO were assessed by physicians to have no pain or only mild pain at the time of consultation; and the mean pain level (on a scale of 0–10) in patients with AS and PsA was 2.7 (SD 2.3) and 2.5 (SD 2.1). Overall, most physicians (RA, 89.7%; AS, 97.4%; PsA, 95.5%; PsO, 95.6%) reported being satisfied with the disease control provided by ABP 501 treatment (Table 1).

Of the ABP 501 initiators ($n = 868$), a subgroup of 207 patients completed the voluntary patient-reported questionnaire at the time of consultation. Most (RA, 86.3%; AS, 100.0%; PsA, 89.2%; PsO, 98.3%) reported being satisfied with the ABP 501 treatment regimen. While on treatment, the mean EQ-VAS and EQ-5D-5L utility scores were in the range 73.7–81.3 and 0.86–0.95, respectively, across disease indications (Table 2). Specifically, the five EQ-5D-5L domain utility indices (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) consistently suggested minimal impact of disease on HRQoL across all indications on the basis of patients' self-assessment. In addition, the median overall activity impairment reported in the WPAI questionnaire was 20.0%

Table 2 Patient self-reported measures of health-related quality of life and satisfaction for patients who initiated adalimumab product (ABP 501 or reference product (RP)) as the first advanced therapy

	Rheumatoid arthritis (RA)		Ankylosing spondylitis (AS)		Psoriatic arthritis (PsA)		Psoriasis (PsO)	
	ABP 501 initiators	**RP initiators**	**ABP 501 initiators**	**RP initiators**	**ABP 501 initiators**	**RP initiators**	**ABP 501 initiators**	**RP initiators**
Patient-reported satisfaction with current treatment, *n* (%)	*n* = 51 44 (86.3)	*n* = 61 49 (80.3)	*n* = 26 26 (100.0)	*n* = 24 21 (87.5)	*n* = 65 58 (89.2)	*n* = 21 18 (85.7)	*n* = 58 57 (98.3)	*n* = 8 6 (75.0)
EQ-VAS, mean (SD)	*n* = 48 76.1 (17.9)	*n* = 63 68.7 (17.9)	*n* = 29 75.9 (18.2)	*n* = 21 65.4 (24.8)	*n* = 64 73.7 (18.4)	*n* = 21 75.6 (18.7)	*n* = 57 81.3 (12.6)	*n* = 8 78.0 (18.9)
EQ-5D-5L German Tariff, mean (SD)	*n* = 52 0.88 (0.13)	*n* = 63 0.88 (0.11)	*n* = 29 0.88 (0.15)	*n* = 23 0.83 (0.20)	*n* = 66 0.86 (0.19)	*n* = 20 0.86 (0.13)	*n* = 58 0.95 (0.08)	*n* = 8 0.92 (0.11)
EQ-5D-5L domain: mobility, *n* (%)	*n* = 53	*n* = 63	*n* = 29	*n* = 23	*n* = 66	*n* = 21	*n* = 58	*n* = 8
I have no problems in walking about	31 (58.5)	48 (76.2)	16 (55.2)	14 (60.9)	40 (60.6)	13 (61.9)	50 (86.2)	7 (87.5)
I have slight problems in walking about	17 (32.1)	13 (20.6)	8 (27.6)	7 (30.4)	22 (33.3)	7 (33.3)	7 (12.1)	1 (12.5)
I have moderate problems in walking about	5 (9.4)	2 (3.2)	4 (13.8)	0 (0.0)	2 (3.0)	1 (4.8)	1 (1.7)	0 (0.0)

Table 2 continued

	Rheumatoid arthritis (RA)		Ankylosing spondylitis (AS)		Psoriatic arthritis (PsA)		Psoriasis (PsO)	
	ABP 501 initiators	**RP initiators**	**ABP 501 initiators**	**RP initiators**	**ABP 501 initiators**	**RP initiators**	**ABP 501 initiators**	**RP initiators**
I have severe problems in walking about	0 (0.0)	0 (0.0)	1 (3.4)	2 (8.7)	2 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)
I am unable to walk	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
EQ-5D-5L domain: self-care, *n* (%)	*n* = 53	*n* = 63	*n* = 29	*n* = 24	*n* = 66	*n* = 21	*n* = 58	*n* = 8
I have no problems washing or dressing myself	37 (69.8)	52 (82.5)	22 (75.9)	15 (62.5)	48 (72.7)	15 (71.4)	54 (93.1)	7 (87.5)
I have slight problems washing or dressing myself	11 (20.8)	8 (12.7)	5 (17.2)	5 (20.8)	14 (21.2)	5 (23.8)	4 (6.9)	1 (12.5)
I have moderate problems washing or dressing myself	5 (9.4)	3 (4.8)	2 (6.9)	4 (16.7)	2 (3.0)	1 (4.8)	0 (0.0)	0 (0.0)
I have severe problems washing or dressing myself	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (3.0)	0 (0.0)	0 (0.0)	0 (0.0)
I am unable to wash or dress myself	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Table 2 continued

	Rheumatoid arthritis (RA)		Ankylosing spondylitis (AS)		Psoriatic arthritis (PsA)		Psoriasis (PsO)	
	ABP 501 initiators	**RP initiators**	**ABP 501 initiators**	**RP initiators**	**ABP 501 initiators**	**RP initiators**	**ABP 501 initiators**	**RP initiators**
EQ-5D-5L domain: usual activities, *n* (%)	*n* = 53	*n* = 63	*n* = 29	*n* = 24	*n* = 66	*n* = 21	*n* = 58	*n* = 8
I have no problems doing my usual activities	21 (39.6)	32 (50.8)	14 (48.3)	7 (29.2)	35 (53.0)	8 (38.1)	52 (89.7)	6 (75.0)
I have slight problems doing my usual activities	26 (49.1)	23 (36.5)	9 (31.0)	12 (50.0)	22 (33.3)	8 (38.1)	5 (8.6)	2 (25.0)
I have moderate problems doing my usual activities	4 (7.5)	8 (12.7)	5 (17.2)	4 (16.7)	8 (12.1)	5 (23.8)	1 (1.7)	0 (0.0)
I have severe problems doing my usual activities	2 (3.8)	0 (0.0)	1 (3.4)	1 (4.2)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)
I am unable to do my usual activities	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
EQ-5D-5L domain: pain/discomfort, *n* (%)	*n* = 53	*n* = 63	*n* = 29	*n* = 23	*n* = 66	*n* = 20	*n* = 58	*n* = 8

Table 2 continued

	Rheumatoid arthritis (RA)		Ankylosing spondylitis (AS)		Psoriatic arthritis (PsA)		Psoriasis (PsO)	
	ABP 501 initiators	**RP initiators**	**ABP 501 initiators**	**RP initiators**	**ABP 501 initiators**	**RP initiators**	**ABP 501 initiators**	**RP initiators**
I have no pain or discomfort	17 (32.1)	20 (31.7)	12 (41.4)	4 (17.4)	22 (33.3)	3 (15.0)	39 (67.2)	4 (50.0)
I have slight pain or discomfort	26 (49.1)	27 (42.9)	13 (44.8)	11 (47.8)	29 (43.9)	12 (60.0)	15 (25.9)	2 (25.0)
I have moderate pain or discomfort	9 (17.0)	14 (22.2)	3 (10.3)	6 (26.1)	12 (18.2)	4 (20.0)	4 (6.9)	2 (25.0)
I have severe pain or discomfort	1 (1.9)	2 (3.2)	1 (3.4)	2 (8.7)	3 (4.5)	1 (5.0)	0 (0.0)	0 (0.0)
I have extreme pain or discomfort	0 (0.0)	0 (0.0)	0 (0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
EQ-5D-5L domain: anxiety/depression, *n* (%)	*n* = 52	*n* = 63	*n* = 29	*n* = 24	*n* = 66	*n* = 21	*n* = 58	*n* = 8
I am not anxious or depressed	34 (65.4)	26 (41.3)	21 (72.4)	17 (70.8)	41 (62.1)	16 (76.2)	40 (69.0)	5 (62.5)
I am slightly anxious or depressed	13 (25.0)	26 (41.3)	7 (24.1)	5 (20.8)	16 (24.2)	3 (14.3)	13 (22.4)	2 (25.0)
I am moderately anxious or depressed	5 (9.6)	11 (17.5)	1 (3.4)	2 (8.3)	6 (9.1)	2 (9.5)	4 (6.9)	1 (12.5)

Table 2 continued

	Rheumatoid arthritis (RA)		Ankylosing spondylitis (AS)		Psoriatic arthritis (PsA)		Psoriasis (PsO)	
	ABP 501 initiators	**RP initiators**	**ABP 501 initiators**	**RP initiators**	**ABP 501 initiators**	**RP initiators**	**ABP 501 initiators**	**RP initiators**
I am severely anxious or depressed	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (4.5)	0 (0.0)	1 (1.7)	0 (0.0)
I am extremely anxious or depressed	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
WPAI: overall work impairment, median, % (IQR)*	*n* = 26 13.6 (10.0, 30.0)	*n* = 27 20.0 (10.0, 30.0)	*n* = 21 20.0 (10.0, 30.0)	*n* = 14 20.0 (10.0, 20.0)	*n* = 39 10.0 (0.0, 38.2)	*n* = 11 10.0 (0.0, 40.0)	*n* = 34 0.0 (0.0, 20.0)	*n* = 5 0.0 (0.0, 0.0)
WPAI: absenteeism, median, % (IQR)*	*n* = 26 0.0 (0.0, 0.0)	*n* = 29 0.0 (0.0, 0.0)	*n* = 21 0.0 (0.0, 0.0)	*n* = 14 0.0 (0.0, 0.0)	*n* = 39 0.0 (0.0, 0.0)	*n* = 11 0.0 (0.0, 0.0)	*n* = 34 0.0 (0.0, 0.0)	*n* = 5 0.0 (0.0, 0.0)
WPAI: presenteeism, median, % (IQR)*	*n* = 34 10.0 (10.0, 20.0)	*n* = 46 20.0 (10.0, 40.0)	*n* = 25 10.0 (10.0, 20.0)	*n* = 17 20.0 (10.0, 20.0)	*n* = 46 10.0 (0.0, 30.0)	*n* = 14 20.0 (10.0, 20.0)	*n* = 42 5.0 (0.0, 20.0)	*n* = 6 0.0 (0.0, 0.0)
WPAI: activity impairment, median, % (IQR)	*n* = 52 20.0 (10.0, 30.0)	*n* = 63 20.0 (10.0, 50.0)	*n* = 29 20.0 (0.0, 30.0)	*n* = 24 30.0 (15.0, 35.0)	*n* = 65 20.0 (10.0, 40.0)	*n* = 21 20.0 (10.0, 40.0)	*n* = 58 10.0 (0.0, 30.0)	*n* = 8 0.0 (0.0, 25.0)

ABP 501 initiators—patients who were receiving ABP 501 as their first advanced therapy. RP initiators—patients who were receiving the reference product adalimumab as their first advanced therapy. Sample sizes vary as a result of missing data

AS ankylosing spondylitis, *EQ-VAS* EuroQoL Visual Analog Scale, *IQR* interquartile range, *PsA* psoriatic arthritis, *PsO* psoriasis, *RA* rheumatoid arthritis, *RP* reference product, *SD* standard deviation, *WPAI* work productivity and activity impairment

*Excludes non-working patients

for patients with RA, AS, and PsA and 10.0% for patients with PsO. Patients who were working reported 13.6%, 20.0%, 10.0%, and 0.0% overall work impairment in RA, AS, PsA, and PsO, respectively, and 0.0% work time missed due to their condition across all disease indications (Table 2).

Reference Product (RP) Initiators

A cohort of 265 patients who initiated adalimumab RP as their first AT and remained on RP therapy at the time of consultation (referred to as "RP initiators") was included in the analysis (RA, $n=148$; AS, $n=37$; PsA, $n=52$; PsO, $n=28$). Overall, patient demographics, clinical status, satisfaction levels, and self-reported assessment of HRQoL appeared to be similar between ABP 501 initiators and RP initiators (Tables 1 and 2). However, we did observe numerical differences in treatment patterns, for example, over 70% of patients with RA received ABP 501 in combination with csDMARDs or steroids while about half of RP initiators who had RA received RP as monotherapy. Time from diagnosis to initiation of adalimumab therapy (as the first AT) was almost doubled in ABP 501 initiators relative to RP initiators among patients with AS, PsA, or PsO.

RP-ABP 501 Switchers

Among the RP-ABP 501 switchers, the most commonly reported reasons by physicians for switching to ABP 501 were related to formulary-driven switch (RA, 27.0%; AS, 58.2%; PsA, 47.1%; PsO, 49.1%), factors relating to costs such as financial reasons (RA, 36.5%), insurance restrictions (AS, 34.2%; PsA, 37.8%; PsO, 15.5%), or fewer administrative hurdles (RA, 22.2%; AS, 11.4%; PsA, 12.8%) (Fig. 1).

At the time of consultation, switchers had been treated with ABP 501 therapy for a median of 11.2–15.3 months across indications, following the switch from the treatment with adalimumab RP for a median of 25.9–28.6 months in patients with RA, AS, or PsO, and for a median

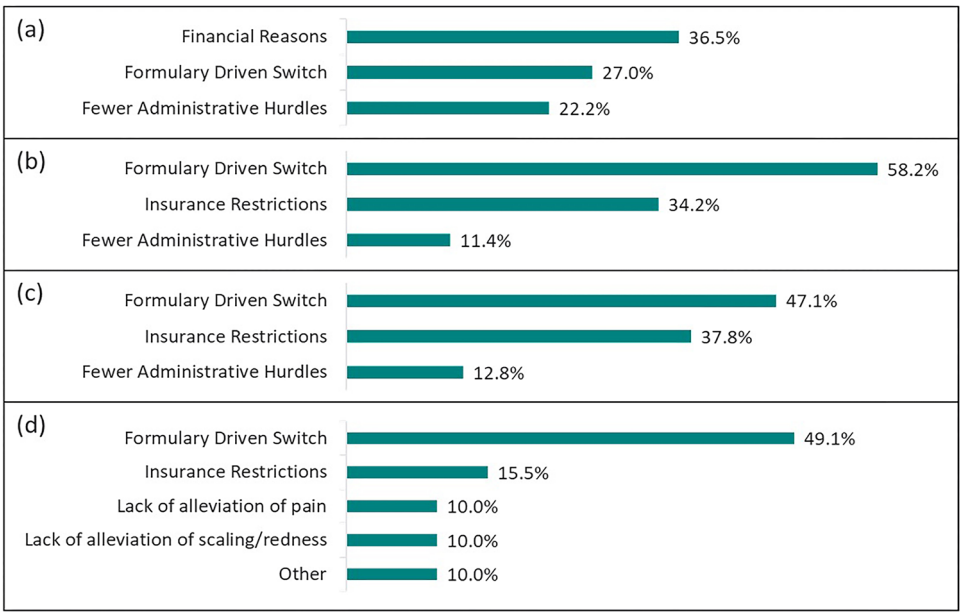

Fig. 1 Top three physician-reported reasons for switching from adalimumab reference product to ABP 501. **a** Rheumatoid arthritis (RA) switchers, $n=63$. **b** Ankylosing spondylitis (AS) switchers, $n=79$. **c** Psoriatic arthritis (PsA) switchers, $n=172$. **d** Psoriasis (PsO) switchers, $n=110$. Multiple choice answer, options varied between indications

Table 3 Physician-reported patient demographics, treatment, and clinical characteristics of patients who switched from adalimumab reference product to ABP 501 (RP-ABP 501 switchers)

	Rheumatoid arthritis (RA) **RP-ABP 501 switchers**	**Ankylosing spondylitis (AS)** **RP-ABP 501 switchers**	**Psoriatic arthritis (PsA)** **RP-ABP 501 switchers**	**Psoriasis (PsO)** **RP-ABP 501 switchers**
Patient count, *n*	63	80	173	112
Demographics				
Age, mean (SD)	51.6 (11.2)	45.8 (12.4)	47.1 (11.0)	46.2 (13.7)
Sex, male, *n* (%)	29 (46.0)	66 (82.5)	68 (39.3)	69 (61.6)
Ethnicity, White, *n* (%)	55 (87.3)	74 (92.5)	163 (94.2)	103 (92.0)
Treatment				
Time from diagnosis to first receipt of adalimumab product (RP), months, median (IQR)[a]	28.6 (12.8, 49.8)	15.1 (5.0, 53.9)	17.9 (4.8, 37.1)	37.6 (15.0, 104.3)
Time duration on current ABP 501, months, median (IQR)	12.4 (6.5, 19.1)	15.3 (8.7, 19.5)	14.1 (5.5, 18.8)	11.2 (4.4, 20.1)
Time duration on RP prior to switch to ABP 501, months, median (IQR)	28.6 (10.6, 48.4)	25.9 (10.8, 58.5)	12.9 (6.7, 27.2)	27.8 (13.6, 54.0)
ABP 501 monotherapy, *n* (%)	14 (22.2)	69 (86.3)	136 (78.6)	80 (71.4)
ABP 501 in combination therapy with conventional therapy, *n* (%)				
Any combination	49 (77.8)	11 (13.8)	37 (21.4)	32 (28.6)
csDMARD	37 (58.7)	2 (2.5)	27 (15.6)	5 (4.5)
Steroid	1 (1.6)	0 (0.0)	3 (1.7)	19 (17.0)
Clinical characteristics				
Disease severity at time of consultation, *n* (%)				
Mild	53 (84.1)	60 (75.0)	141 (81.5)	98 (87.5)
Moderate	10 (15.9)	20 (25.0)	29 (16.8)	12 (10.7)
Severe	0 (0.0)	0 (0.0)	3 (1.7)	2 (1.8)

Table 3 continued

	Rheumatoid arthritis (RA) RP-ABP 501 switchers	Ankylosing spondylitis (AS) RP-ABP 501 switchers	Psoriatic arthritis (PsA) RP-ABP 501 switchers	Psoriasis (PsO) RP-ABP 501 switchers
Physician-reported patient pain, *n* (%)				
None	28 (44.4)	NA	NA	86 (76.8)
Mild	27 (42.9)			21 (18.8)
Moderate	8 (12.7)			5 (4.5)
Severe	0 (0.0)			0 (0.0)
Physician-reported patient pain, mean (SD)*	NA	2.1 (1.4)	1.8 (1.7)	NA
Physician-reported satisfaction with current treatment, *n* (%)	60 (95.3)	79 (98.8)	170 (98.3)	104 (93.7)

RP-ABP 501 switchers—patients who were receiving ABP 501 following a direct switch from the adalimumab reference product as their first advanced therapy

AS ankylosing spondylitis, *AT* advanced therapy, *csDMARD* conventional synthetic disease-modifying anti-rheumatic drug, *IQR* interquartile range, *NA* not applicable, *PsA* psoriatic arthritis, *PsO* psoriasis, *RA* rheumatoid arthritis, *RP* reference product, *SD* standard deviation

*Numerical scale rating, ranging from 0 to 10, where 0 was none and 10 was the highest

[a]RA, $n = 58$; AS, $n = 73$; PsA, $n = 148$; PsO, $n = 72$

of 12.9 months in patients with PsA (Table 3). Most switchers (AS, 86.3%; PsA, 78.6%; PsO, 71.4%) were receiving ABP 501 as monotherapy; while in patients with RA, 77.8% of switchers were receiving ABP 501 as part of a combination therapy, mainly alongside a csDMARD (58.7%). Physicians reported that the majority of switchers were experiencing mild disease (RA, 84.1%; AS, 75.0%; PsA, 81.5%; PsO, 87.5%) at the time of consultation; 87.3% of patients with RA and 95.5% of patients with PsO were evaluated by physicians to have no pain or mild pain, and for patients with AS and PsA, physician-assessed mean pain scores (on a scale ranging from 0 to 10) were 2.1 (SD 1.4) and 1.8 (SD 1.7), respectively. Overall, most physicians reported that they were satisfied with the disease control provided by current ABP 501 treatment after the switch from the RP (RA, 95.3%; AS, 98.8%; PsA, 98.3%; PsO, 93.7%) (Table 3).

Of the RP-ABP 501 switchers, a subgroup of 111 patients completed the voluntary patient-reported questionnaires, of which 100.0% with RA, 94.7% with AS, 97.4% with PsA, and 94.9% with PsO reported being satisfied with their ABP 501 treatment regimen. Mean EQ-VAS and EQ-5D-5L score reported by patients ranged from 70.4 to 79.2 and 0.88 to 0.94, respectively, indicating an overall good HRQoL among switchers across indications (Table 4). Additionally, the five domain utility scores of EQ-5D-5L consistently suggested minimal impairment in mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Across indications, patient self-reported WPAI scores showed a median of 10.0–20.0% overall

Table 4 Patient self-reported measures of health-related quality of life and satisfaction for patients who switched from adalimumab reference product to ABP 501 (RP-ABP 501 switchers)

	Rheumatoid arthritis (RA) **RP-ABP 501 switchers**	**Ankylosing spondylitis (AS)** **RP-ABP 501 switchers**	**Psoriatic arthritis (PsA)** **RP-ABP 501 switchers**	**Psoriasis (PsO)** **RP-ABP 501 switchers**
Patient-reported satisfaction with current treatment, *n* (%)	*n* = 12 12 (100.0)	*n* = 19 18 (94.7)	*n* = 39 38 (97.4)	*n* = 39 37 (94.9)
EQ-VAS, mean (SD)	*n* = 13 77.9 (18.2)	*n* = 19 70.4 (20.8)	*n* = 39 77.5 (14.5)	*n* = 39 79.2 (16.1)
EQ-5D-5L German Tariff, mean (SD), mean (SD)	*n* = 13 0.92 (0.09)	*n* = 18 0.88 (0.10)	*n* = 40 0.90 (0.08)	*n* = 39 0.94 (0.07)
EQ-5D-5L domain: mobility, *n* (%)	*n* = 13	*n* = 19	*n* = 40	*n* = 39
I have no problems in walking about	9 (69.2)	12 (63.2)	26 (65.0)	33 (84.6)
I have slight problems in walking about	3 (23.1)	7 (36.8)	9 (22.5)	5 (12.8)
I have moderate problems in walking about	1 (7.7)	0 (0.0)	5 (12.5)	1 (2.6)
I have severe problems in walking about	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
I am unable to walk	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
EQ-5D-5L domain: self-care, *n* (%)	*n* = 13	*n* = 19	*n* = 40	*n* = 39
I have no problems washing or dressing myself	10 (76.9)	12 (63.2)	30 (75.0)	37 (94.9)
I have slight problems washing or dressing myself	3 (23.1)	6 (31.6)	9 (22.5)	2 (5.1)
I have moderate problems washing or dressing myself	0 (0.0)	1 (5.3)	1 (2.5)	0 (0.0)
I have severe problems washing or dressing myself	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Table 4 continued

	Rheumatoid arthritis (RA) RP-ABP 501 switchers	Ankylosing spondylitis (AS) RP-ABP 501 switchers	Psoriatic arthritis (PsA) RP-ABP 501 switchers	Psoriasis (PsO) RP-ABP 501 switchers
I am unable to wash or dress myself	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
EQ-5D-5L domain: usual activities, *n* (%)	*n* = 13	*n* = 19	*n* = 40	*n* = 39
I have no problems doing my usual activities	8 (61.5)	7 (36.8)	22 (55.0)	31 (79.5)
I have slight problems doing my usual activities	3 (23.1)	8 (42.1)	13 (32.5)	7 (17.9)
I have moderate problems doing my usual activities	2 (15.4)	3 (15.8)	5 (12.5)	1 (2.6)
I have severe problems doing my usual activities	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
I am unable to do my usual activities	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)
EQ-5D-5L domain: pain/discomfort, *n* (%)	*n* = 13	*n* = 19	*n* = 40	*n* = 39
I have no pain or discomfort	7 (53.8)	3 (15.8)	13 (32.5)	21 (53.8)
I have slight pain or discomfort	4 (30.8)	12 (63.2)	21 (52.5)	13 (33.3)
I have moderate pain or discomfort	2 (15.4)	4 (21.1)	6 (15)	5 (12.8)
I have severe pain or discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
I have extreme pain or discomfort	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
EQ-5D-5L domain: anxiety/depression, *n* (%)	*n* = 13	*n* = 18	*n* = 40	*n* = 39

Table 4 continued

	Rheumatoid arthritis (RA) RP-ABP 501 switchers	Ankylosing spondylitis (AS) RP-ABP 501 switchers	Psoriatic arthritis (PsA) RP-ABP 501 switchers	Psoriasis (PsO) RP-ABP 501 switchers
I am not anxious or depressed	10 (76.9)	17 (94.4)	30 (75.0)	29 (74.4)
I am slightly anxious or depressed	2 (15.4)	1 (5.6)	8 (20.0)	9 (23.1)
I am moderately anxious or depressed	1 (7.7)	0 (0.0)	2 (5.0)	1 (2.6)
I am severely anxious or depressed	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
I am extremely anxious or depressed	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
WPAI: overall work impairment, median, % (IQR)*	*n* = 5 10.0 (0.0, 10.0)	*n* = 9 10.0 (10.0, 30.0)	*n* = 22 15.0 (0.0, 20.0)	*n* = 17 0.0 (0.0, 20.0)
WPAI: absenteeism, median, % (IQR)*	*n* = 5 0.0 (0.0, 0.0)	*n* = 9 0.0 (0.0, 0.0)	*n* = 22 0.0 (0.0, 0.0)	*n* = 17 0.0 (0.0, 0.0)
WPAI: presenteeism, median, % (IQR)*	*n* = 7 10.0 (0.0, 10.0)	*n* = 11 10.0 (10.0, 30.0)	*n* = 28 15.0 (0.0, 20.0)	*n* = 24 0.0 (0.0, 20.0)
WPAI: activity impairment, median, % (IQR)	*n* = 13 10.0 (10.0, 30.0)	*n* = 19 20.0 (10.0, 30.0)	*n* = 40 20.0 (10.0, 30.0)	*n* = 39 10.0 (0.0, 20.0)

RP-ABP 501 switchers—patients who were receiving ABP 501 following a direct switch from the adalimumab reference product as their first advanced therapy. Sample sizes vary as a result of missing data

AS ankylosing spondylitis, *EQ-VAS* EuroQoL Visual Analog Scale, *IQR* interquartile range, *PsA* psoriatic arthritis, *PsO* psoriasis, *RA* rheumatoid arthritis, *SD* standard deviation, *WPAI* work productivity and activity impairment

*Excludes non-working patients

activity impairment, and among those who were working, 0.0–15.0% overall impairment, 0.0% work time missed, and 0.0–15.0% impairment while working due to their disease conditions were reported (Table 4).

DISCUSSION

Our current analysis of the Adelphi DSP cross-sectional survey data showed that both patients and their treating physicians were highly satisfied with the disease control provided by ABP 501 therapy, regardless of prior use of adalimumab RP. The real-world experience reported by both patients and physicians supports the

initiation of and switching to adalimumab biosimilar ABP 501 in various approved indications, including those approved on the basis of extrapolation (i.e., PsA, AS). Across studied indications, patients who initiated biosimilar ABP 501 as the first AT were not observed to experience substantial differences from those who initiated adalimumab RP in terms of patient demographics, overall disease control (assessed by physicians), and patient self-reported quality of life outcomes. Our findings, however, appeared to show that the time from disease diagnosis to initiation of adalimumab product in patients with AS, PsA, and PsO was almost twice as long in ABP 501 initiators compared to RP initiators. Small sample sizes and the descriptive nature of the study prevent the drawing of definitive conclusions; perhaps patients who would ideally have been prescribed the RP earlier were able to initiate adalimumab treatment when the biosimilar ABP 501 became available. This aligns with previous findings that the market availability of biosimilars provided alternative treatment options for patients access to biological medicines [31–35]. In our study, physician-reported reasons for switching to ABP 501 were related to formulary-driven switch, financial reasons, insurance restrictions, or fewer administrative hurdles. As data reported in this study were collected in Europe, issues such as administrative hurdles, insurance restrictions, and financial reasons may not be as relevant or generalizable to other regions/countries. Future studies of cost analysis in relation to switching between RP and biosimilars could be of interest.

Despite the potential to reduce healthcare costs, several barriers to utilization of biosimilars remained and required further efforts to address. The adoption of biosimilars may be especially challenging for patients and healthcare providers who have had positive experiences with the reference product, and they may be reluctant to switch to a biosimilar because of unfamiliarity and concerns about effectiveness and safety which can result in a nocebo effect among patients. A previous study of Dutch patients with RA, PsA, and AS found that patients who switched from the infliximab originator to its biosimilar had a 24% discontinuation rate after 6 months, mainly due to subjective reasons only (not the objective assessment, i.e., swollen joint count or C-reactive protein levels) that are possibly explained by the nocebo effect [36]. A recently published prospective observational study in Canadian patients with inflammatory bowel disease also reported frequent nocebo complaints within 6 months of a non-medical switch from infliximab or adalimumab originator to its respective biosimilars, although clinical efficacy, biomarkers, or anti-drug antibodies were well maintained [37]. In the current analysis, we showed that the majority of switched patients (75.0–87.5% across studied disease indications) had mild disease severity as assessed by their physicians at the time of data collection. Our study did not analyze the nocebo effect, data on persistence of efficacy were not assessed as a result of the cross-sectional nature of data collection, and data on neutralizing antibody development were not collected. However, over 93% of physicians and at least 95% of switched patients reported being satisfied with the disease control provided by ABP 501. A subgroup of switched patients additionally provided self-assessed HRQoL and their reported EQ-VAS and EQ-5D-5L scores were within the score range reported in the general population [38, 39], indicating minimal impact on HRQoL while receiving ABP 501 following the switch from the reference product. Such evidence from the real-world setting can help instill confidence in both physicians and patients about biosimilar switch. This study only focused on the use of ABP 501 in either patients who initiated with the biosimilar or who switched to ABP 501 after previously being prescribed the RP at first line. Future studies will be of interest to understand clinical outcomes and any potential differences between first-line users of biologics or biosimilars and those who received treatments at the second or subsequent lines.

This analysis of the real-world data, without protocol-induced visits and restrictive inclusion criteria for patients, has allowed an assessment of the use of ABP 501 in clinical practices outside of clinical trials. The same data collection methodology used in DSP surveys has been previously published and validated [21–24] and was used across countries, allowing for grouped European analysis (although slight variations in

the question structure meant different calculations for time on treatment for patients with PsO, as described in the methods). However, our study has several limitations. First, the samples may not be representative of the entire patient populations as the methodology included consecutively specialist-consulting patients, and patients who consult their physicians more frequently were more likely to be included in the study. Second, although there were minimal inclusion criteria for physician selection (those with a preset active clinical load), willingness to participate will have influenced inclusion in the study. In addition, recall bias is not uncommon in survey data collection as the quality of data is largely dependent on the accurate reporting by participants. However, participating physicians were asked to complete the survey forms at the time of each patient's clinical consultation and by referring to patient's medical record data to minimize this bias. As completion of the patient-reported questionnaire was voluntary, this led to smaller sample sizes for patient-reported outcomes, with data missing for some variables if questions were not answered in full.

CONCLUSIONS

Across RA, AS, PsA, and PsO indications, patients experienced overall positive treatment outcomes when receiving biosimilar ABP 501, and both physicians and patients reported being satisfied with the disease control provided by ABP 501 treatment, regardless of prior exposure to reference product. Our findings add to the growing body of real-world experience with biosimilar use which help address barriers to utilization due to lack of awareness and concerns about inadequate efficacy from both patients and physicians, especially for indications approved on the principle of extrapolation and for patients who switch from the reference product.

ACKNOWLEDGEMENTS

The authors would like to thank the physicians and patients who participated in the Adelphi Real World RA, SpA and PsO DSPs.

Medical Writing, Editorial, and Other Assistance. Editorial and medical writing support on behalf of Adelphi Real World were provided by Gary Sidgwick, PhD of Adelphi Real World, Bollington, UK under the guidance of the authors and in accordance with Good Publication Practice 2022 (GPP 2022) guidelines (https://www.ismpp.org/gpp-2022). Additional medical writing support under the guidance of the authors was provided by Sue Libretto, PhD, of Sue Libretto Publications Consultant Ltd (Hertfordshire, UK), on behalf of Adelphi Real World. The authors would also like to thank Megan Hughes (an employee of Adelphi Real World at the time of the study) for her support in the development of the paper.

Author Contributions. Adelphi Real World undertook data collection as part of independent surveys, entitled the Adelphi RA, SpA and PsO DSPs. The original surveys were not influenced by Amgen through either contribution to the design of questionnaires or data collection. Data used in the analysis described here came from the Adelphi RA, SpA and PsO DSPs. The DSP is a wholly owned Adelphi product. The DSPs have multiple subscribers, of which Amgen Inc. was one. Ran Jin: study design, data interpretation, review, writing, editing. James M Haughton: data interpretation, writing, review, editing. Emily J Goddard: data interpretation, writing, review, editing. Delphine Courmier: study design, data interpretation, review. Waldemar Radziszewski: data interpretation, review. Rachael H Meadows: formal analysis, review. James Piercy: study design, data interpretation, review. Stanley Cohen: data interpretation, review. All authors had access to relevant data and participated in the drafting, review, and approval of this publication. No honoraria or payments were made for authorship.

Funding. Data collection was undertaken by Adelphi Real World as part of independent surveys, entitled the Adelphi RA, SpA and PsO DSPs. The DSP is a wholly owned Adelphi Real World product. Amgen Inc. was one of multiple subscribers to the DSPs. The analysis presented here was conducted as part of the subscription to the DSP dataset purchased by Amgen Inc. The journal's article processing fees for this paper were paid for by Amgen Inc.

Data Availability. All data relevant to the study are included in the article or uploaded as supplementary information. All data, i.e. methodology, materials, data and data analysis, that support the findings of this survey are the intellectual property of Adelphi Real World. All requests for access should be addressed directly to Emily Goddard at emily.goddard@adelphigroup.com.

Declarations

Conflict of Interest. Emily J Goddard, James M Haughton, James Piercy and Rachael H Meadows are employees of Adelphi Real World. Ran Jin and Waldemar Radziszewski are employees of Amgen Inc., Thousand Oaks, CA, USA, and may own stock and/or hold stock options in Amgen Inc. Delphine Courmier was an employee of Amgen Inc., Thousand Oaks, CA, USA at the time of this study. At the time of publication, Delphine Courmier was an employee of Organon, Jersey City, NJ, USA. Stanley Cohen is an investigator and consultant for Amgen.

Ethical Approval. The data collection methodology and survey questionnaires were reviewed and approved by the Western Institutional Review Board (protocol numbers #1-1253914-1 [RA 2020 wave], #20210318 [SpA]) or Pearl Institutional Review Board (protocol numbers #21-ADRW-104 [RA 2021/2022 wave], #21-ADRW-124 [PsO]). Data collection was undertaken in line with European Pharmaceutical Marketing Research Association guidelines [28]; and the survey was performed in full accordance with relevant legislation at the time of data collection, including the US Health Insurance Portability and Accountability Act 1996 [29] and Health Information Technology for Economic and Clinical Health Act legislation [30], and in accordance with the principles stated in the Declaration of Helsinki. Using a checkbox, patients provided informed consent take part in the survey, and for the use of their anonymized and aggregated data for research purposes.

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