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ORIGINAL RESEARCH

Effectiveness, Safety, and Drug Survival of Bimekizumab in Chronic Plaque Psoriasis over 2 Years: Real-World Experience from Northern Italy

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ABSTRACT

***Introduction*:** Bimekizumab, a dual interleukin (IL)-17A and IL-17F inhibitor, has demonstrated high efficacy in clinical trials for moderate-to-severe plaque psoriasis. However, real-world evidence regarding its long-term effectiveness, safety, and treatment persistence up to 2 years remains limited. This study evaluates these outcomes in a routine clinical setting.

***Methods*:** We conducted a retrospective, multicenter, real-world study across three Italian referral centers, including 126 adult patients with moderate-to-severe plaque psoriasis treated with bimekizumab. Efficacy was assessed by the proportion of patients achieving Psoriasis Area and Severity Index (PASI)75, PASI90, and PASI100 up to 104 weeks. Firth's penalized multivariable logistic regression was utilized to identify independent predictors of PASI100 at weeks 16 and 52. Drug survival was estimated using Kaplan–Meier analysis. Safety was evaluated through the incidence of treatment-emergent adverse events (TEAEs) expressed per 100 patient-years.

***Results*:** Bimekizumab demonstrated rapid and sustained effectiveness with complete skin clearance (PASI100) being achieved by 61.5%, 80.0%, and 76.5% of patients at week 16, 52, and 104, respectively. At week 16, penalized multivariable analysis identified palmo-plantar involvement, nail psoriasis, and concomitant proton pump inhibitor (PPI) use as independent negative predictors of PASI100. By week 52, only palmo-plantar involvement remained a significant negative predictor. The overall cumulative probability of drug survival at 2 years was 72.2%. Stratified analyses revealed that biologic-naïve patients exhibited a significantly higher 2-year retention rate compared to bio-experienced individuals (91.5% versus 64.0%, p=0.0083), whereas age and body mass index (BMI) did not significantly affect treatment persistence. Clinically significant TEAEs occurred at an incidence rate of 16.8 per 100 patient-years, predominantly driven by candidiasis (8.1 per 100 patient-years) and eczema (5.8 per 100 patient-years). The overall discontinuation rate was 22.2%.

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Conclusions: Bimekizumab represents a highly effective and durable therapeutic option for moderate-to-severe plaque psoriasis, maintaining robust clinical responses over a 2-year period. While a history of prior biologic failures negatively influences long-term drug survival, high levels of absolute skin clearance are consistently attainable regardless of challenging baseline characteristics such as advanced age or obesity.
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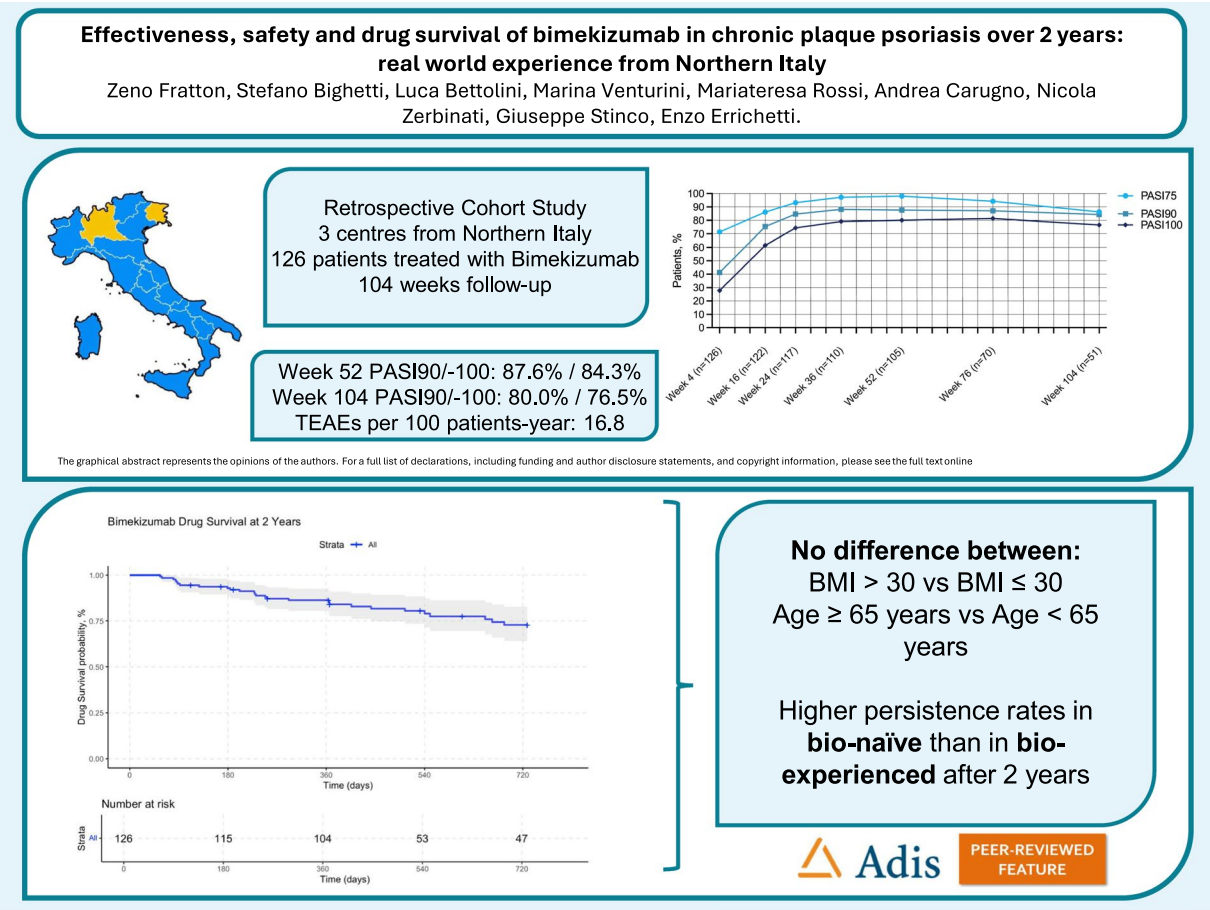


Keywords: Psoriasis; Bimekizumab; Effectiveness; Safety; Drug survival; Real world

Key Summary Points

Why carry out this study?

Real-world evidence regarding the effectiveness, safety, and treatment persistence of bimekizumab over extended periods (up to 2 years) in patients with highly refractory plaque psoriasis remains limited.

We aimed to evaluate the 2-year effectiveness, safety, and drug survival of bimekizumab in routine clinical practice, and identify predictors of complete skin clearance.

What was learned from the study?

Bimekizumab demonstrated rapid and sustained effectiveness, with 80.0% and 76.5% of patients achieving complete skin clearance (PASI100) at week 52 and 104, respectively.

While biologic-naïve patients exhibited an excellent 2-year drug survival rate (91.5%), prior biologic exposure, but not advanced age or obesity, significantly decreased long-term treatment retention (64.0%).

Palmo-plantar involvement, nail psoriasis, and concomitant proton pump inhibitor (PPI) use act as independent negative predictors for achieving early complete skin clearance; however, findings derived from small subgroups, such as PPI users, should be interpreted cautiously as hypothesis-generating.

DIGITAL FEATURES

This article is published with digital features, including an infographic, to facilitate understanding of the article. To view digital features for this article, go to https://doi.org/10.6084/m9.figshare.32628873.

INTRODUCTION

Plaque psoriasis is a chronic, immune-mediated skin disease affecting approximately 2–3% of the global population [1]. Recent advances in targeted therapies, particularly the introduction of biologic agents, have revolutionized the management of this condition, making complete skin clearance an achievable clinical goal for a large proportion of patients [2].

Bimekizumab represents one of the most recently approved biologic options; it is a humanized monoclonal IgG1 antibody that specifically and selectively neutralizes both interleukin (IL)-17A and IL-17F, leveraging a unique dual-targeted mechanism of action [3] The high efficacy and safety profile of bimekizumab have been extensively established in phase III clinical trials BE RADIANT, BE READY, BE VIVID, and BE SURE [4–6], while the BE BRIGHT extension study has confirmed the robustness and durability of its therapeutic effect over the long term [7].

The short- and medium-term effectiveness and safety of bimekizumab in the real world have been confirmed in several studies at different follow-up times [8, 9] and in various special populations, including patients affected by erythrodermic psoriasis or psoriasis involving special sites [10–14]. However, despite the excellent performance demonstrated in real-world experiences up to 52 weeks, real-world evidence regarding the effectiveness, safety, and treatment persistence of bimekizumab over extended periods, such as 2 years, remains limited [15, 16]. Takahashi et al. [15] described the results of a small studies involving 66 patients treated with bimekizumab 320 mg every 4 (Q4W) or 8 weeks (Q8W) as maintenance dose. In the study, bio-experienced patients in the Q4W treatment scheme group achieved Psoriasis Area and Severity Index (PASI)100 faster than bio-naïve patients in the same group but showed a higher loss of effectiveness over 2 years, compared with the bio-naïve group. In the Q8W treatment scheme group, bio-naïve patients responded more rapidly and maintained higher PASI100 rates than bio-experienced patients. While the effectiveness of bimekizumab over 2 years was overall confirmed, PASI100 was maintained by 30% of bio-experienced patients in the latter group after 104 weeks, suggesting that bio-experienced

patients may show less durable responses to bimekizumab treatment.

De Luca et al. [16] investigated the drug survival of bimekizumab in a multicenter retrospective study involving 826 patients over 104 weeks, documenting a treatment persistence of 89.1% at 12 months and 82.4% at 24 months and finding male sex as the only independent predictor of longer drug survival (hazard ratio (HR) 0.67, 95% confidence interval (CI) 0.49–0.90; $p=0.008$).

In a recent Danish registry-based study [17] evaluating the drug survival of several biologics, bimekizumab showed a treatment persistence of 83% (95% CI 79–87%) after 1 year and of 73% (discontinuation risk: 0.27; 95% CI 0.20–0.34) after 2 years, in the bio-experienced group.

In a real-world setting, drug survival represents a useful surrogate index, as it combines continuous effectiveness, long-term safety, and overall drug tolerability [18]. In this context, there is a strong need for new clinical evidence to confirm these long-term outcomes for bimekizumab in daily clinical practice. Therefore, this retrospective study aims to evaluate the 2-year effectiveness, safety, and drug survival of bimekizumab in patients with moderate-to-severe plaque psoriasis in a real-life clinical setting.

METHODS

Study Design and Population

This was a retrospective, multicenter, real-world observational study conducted across three dermatological referral centers in Italy (Udine, Brescia, and Varese). We included adult patients (age > 18 years of age) with moderate-to-severe chronic plaque psoriasis who initiated treatment with bimekizumab between April 2023 and December 2025 in accordance with Italian guidelines [19]. Exclusion criteria included patients treated with bimekizumab for indications other than plaque psoriasis or those concurrently receiving other systemic anti-psoriatic treatments during the observation period. Bimekizumab was administered according to the standard European Medicines Agency (EMA) approved dosing regimen: 320 mg via subcutaneous injection at week 0, 4, 8, 12, and 16, followed by 320 mg every 8 weeks.

The study was conducted in accordance with the ethical standards established by the 1964 Declaration of Helsinki and its later amendments. Ethical approval was obtained from the local Ethics Committee (Comitato Etico Territoriale Lombardia 6, protocol 4710). Written informed consent to participate in the study, for the use of medical records for research purposes, and for the publication of non-identifying data was obtained from all individual participants included in the study.

Data Collection and Outcomes

Clinical and demographic data were systematically extracted from the electronic medical records (EMRs) of the participating centers. The collected variables included patient demographics (age, sex, and body mass index [BMI]), psoriasis disease duration, family history of psoriasis, presence of concomitant psoriatic arthritis (PsA), and the involvement of difficult-to-treat areas (scalp, genitals, palmo-plantar region, and nails). We additionally recorded patients' cardiometabolic and psychiatric comorbidities (e.g., arterial hypertension, diabetes, dyslipidemia, chronic kidney disease, any psychiatric disorder) and their concurrent chronic pharmacological treatments (e.g., statins, anti-hypertensive drugs, proton pump inhibitors, antidiabetic agents). History of prior systemic and biologic therapies (naïve versus bio-experienced, along with the number and type of prior biologic failures) was also documented.

Clinical efficacy was evaluated using the Psoriasis Area and Severity Index (PASI) at baseline and at week 4, 16, 24, 36, 52, 76, and up to 104. The primary efficacy outcomes were the proportions of patients achieving 75%, 90%, and 100% improvement in PASI scores (PASI75, PASI90, and PASI100, respectively). Safety outcomes included the incidence of treatment-emergent adverse events (TEAEs) and the rates and reasons for treatment discontinuation

(adverse events, secondary inefficacy, or voluntary withdrawal). In accordance with our exclusion criteria, no patient received concurrent systemic rescue therapy during the observation period; any patient requiring the introduction of a new systemic anti-psoriatic agent was considered a treatment failure and recorded as a discontinuation due to secondary inefficacy.

Statistical Analysis

Descriptive statistics were used to summarize the baseline characteristics of the study population. Continuous variables are expressed as means and standard deviations (SD) or medians with interquartile ranges (IQR) depending on data distribution, while categorical variables are presented as absolute frequencies and percentages.

Efficacy outcomes were evaluated using an as-observed (AO) approach. The reduction in the number of evaluable patients at later time points (e.g., week 104) was primarily owing to the staggered initiation of bimekizumab treatment across the inclusion period, resulting in administrative censoring, rather than true loss to follow-up or treatment discontinuation.

To identify potential predictors of complete skin clearance (PASI100) at week 16 and 52, univariate logistic regression analyses were initially performed for all baseline variables. Variables yielding a p-value < 0.15 in the univariate analysis, alongside predefined clinically relevant covariates (age, sex, BMI, and biologic-naïve status), were subsequently included in the multivariable models. To account for the limited number of non-events and mitigate the risk of overfitting or quasi-complete separation, Firth's penalized maximum-likelihood logistic regression was utilized for the multivariable analyses. Results are expressed as penalized odds ratios (OR) with their corresponding 95% profile penalized confidence intervals (CI).

Drug survival, defined as the time from bimekizumab initiation to treatment discontinuation for any cause, was estimated using the Kaplan–Meier method. Specifically, the observation period for each patient started on the date of the first bimekizumab administration. An event was defined as the definitive discontinuation of the treatment, with the event date corresponding to the date of withdrawal recorded in the electronic medical records. Patients who were still actively receiving treatment at the end of the study period (31 December 2025), or those who were lost to follow-up, were right-censored at the date of their last available clinical evaluation. Survival curves were generated for the overall cohort and subsequently stratified by patient age (< 65 versus ≥ 65 years), baseline BMI (≤ 30 versus > 30 kg/m^2), and prior biologic exposure (biologic-naïve versus bio-experienced). The log-rank test was utilized to compare survival distributions between these stratified groups.

Microsoft Excel was used for data collection, while GraphPad Prism version 10.6.1 for Mac OS (GraphPad Software, Boston, Massachusetts USA) and R Statistical Software (version 4.4.2, R Foundation for Statistical Computing, Vienna, Austria) were used to generate graphs.

All statistical analyses were performed using R software (version 4.4.2, R Foundation for Statistical Computing, Vienna, Austria). A two-sided p-value < 0.05 was considered statistically significant for the final models.

RESULTS

Baseline Characteristics of the Study Population

A total of 126 patients with moderate-to-severe plaque psoriasis treated with bimekizumab were included in the study. Owing to the staggered enrollment over the observation period, the number of patients with sufficient follow-up to be evaluated for clinical efficacy varied across time points. Specifically, out of the 126 patients included at baseline, data were available for 122 patients at week 16, 117 patients at week 24, 110 patients at week 36, 105 patients at week 52, 70 patients at week 76, and 51 patients who had completed the 104-week follow-up at the time of data cutoff.

The cohort was predominantly male ($n=77$, 61.1%), with a mean age of 50.1 years (±14.6) and a mean BMI of 27.5 kg/m^2 (±5.1). The mean duration of psoriasis was 14.8 years (±11.3). Concomitant psoriatic arthritis (PsA) was present in 26.2% of patients ($n=33$). Involvement of difficult-to-treat areas was highly prevalent, affecting 76.2% of the population, specifically involving the scalp (43.7%), genitals (32.5%), and palms and soles (21.4%). Nail involvement was observed in 37.3% of patients.

The most common comorbidities included hypertension (30.3%), obesity (28.6%), dyslipidemia (13.5%), and diabetes (12.7%). Regarding previous treatments, about one-third of the patients were biologic-naïve (32.5%), while the majority (67.5%) had experienced at least one prior biologic failure, with a mean of 1.7 (±1.2) previous failures per patient among the bio-experienced group. The most frequently used prior biologics were adalimumab (49.2%) and secukinumab (16.7%). Further details regarding the baseline demographic and clinical characteristics of our cohort are described in Table 1.

Clinical Efficacy

Bimekizumab demonstrated a rapid and sustained reduction in disease severity. The mean PASI decreased from a baseline of 13.7 (±9.3) to 2.8 (±3.3) as early as week 4. This improvement deepened over time, with mean PASI scores dropping to 1.1 (±2.0) at week 16 and remaining consistently low (ranging between 0.4 and 0.7) from week 24 through week 104 (Fig. 1).

Clinical response rates were correspondingly high. At week 4, 71.4% of patients had already achieved PASI75, while 41.3% achieved PASI90 and 27.8% achieved complete clearance (PASI100). By week 16 ($n=122$), 86.1%, 75.4%, and 61.5% of patients reached PASI75, PASI90, and PASI100, respectively. Peak efficacy was observed around week 52 ($n=105$), where 98.1% of patients maintained a PASI75 response, 87.6% reached PASI90, and 80.0% achieved PASI100. At the end of the 2-year observation period (week 104, $n=51$), 86.3%, 84.3%, and 76.5% of patients sustained PASI75, PASI90, and PASI100, respectively (Fig. 2).

Predictors of Complete Clearance (PASI100)

To identify factors influencing complete skin clearance, univariate and multivariable logistic regression analyses were conducted at week 16 and 52 (Table 2). On multivariable analysis at week 16, palmo-plantar involvement (OR 0.30; 95% CI 0.10–0.82; $p=0.021$), nail involvement (OR 0.23; 95% CI 0.09–0.53; $p<0.001$), and the concomitant use of proton pump inhibitors (PPI) (OR 0.16; 95% CI 0.03–0.69; $p=0.016$) were identified as independent negative predictors for achieving PASI100. Patient demographics (age, sex, and BMI) and biologic-naïve status (OR 1.17; 95% CI 0.44–3.26; $p=0.751$) did not significantly impact the week-16 complete response.

At week 52, multivariable analysis confirmed that palmo-plantar involvement remained the only strongly significant negative predictor of long-term complete clearance (OR 0.11; 95% CI 0.03–0.40; $p=0.001$). Notably, a history of biologic failures (bio-naïve status OR 0.67; 95% CI 0.20–2.33; $p=0.525$), baseline PASI, BMI, and sex did not preclude the achievement of PASI100 at 1 year.

Drug Survival Analysis

The overall cumulative probability of drug survival was 92.0% (95% CI 87.4–96.9) at 180 days, 84.4% (78.2–91.2) at 360 days, 78.3% (70.8–86.7) at 540 days, and 72.2% (63.5–82.2) at 720 days (Fig. 3). Kaplan–Meier survival curves were generated to evaluate treatment persistence across different patient subpopulations (Fig. 4). Stratification by age groups (<65 years versus ≥65 years) and by BMI (≤30 kg/m^2 versus >30 kg/m^2) revealed no significant differences in treatment retention over the 2-year period. At 720 days, drug survival was 72.5% in the younger cohort compared with 69.0% in the older population, and 71.5% in non-obese patients compared with 73.3% in obese patients (Table 3).

Conversely, stratification by prior biologic exposure revealed a significant divergence in treatment persistence (log-rank $p=0.0083$). Biologic-naïve patients exhibited an excellent drug survival rate, maintaining 91.5% (95% CI

Table 1 Summary of demographic and clinical characteristics of included patients

Study population	
Patients, *n*	126
Age (years), mean (± SD); median [IQR]	50.1 (± 14.6); 50.5 [40.0–60.8]
Sex:	
Male, *n* (%)	77 (61.1%)
Female, *n* (%)	49 (38.9%)
Body mass index (kg/m^2); median [IQR]	27.5 (± 5.1); 26.6 [23.8–30.7]
Psoriasis duration (years), mean (± SD); median [IQR]	14.8 (± 11.3); 12.0 [6.0–21.0]
Psoriasis family history, *n* (%)	42 (33.3%)
Psoriatic arthritis, *n* (%)	33 (26.2%)
Psoriatic arthritis duration (years), mean (± SD); median [IQR]	7.1 (± 6.6); 5.5 [2.0–9.25]
Baseline PASI, mean (± SD); median [IQR]	13.7 (± 9.3); 10.6 [8.0–15.0]
Involvement of difficult to treat areas, *n* (%)	96 (76.2%)
Scalp	55 (43.7%)
Genitals	41 (32.5%)
Palms and soles	27 (21.4%)
Nail involvement, *n* (%)	47 (37.3%)
Comorbidities, *n* (%):	
Hypertension	33 (30.3%)
Obesity	36 (28.6%)
Dyslipidemia/hypercholesterolemia	17 (13.5%)
Diabetes	16 (12.7%)
Any psychiatric disorder*	15 (11.9%)
Asthma and/or allergic rhinitis	11 (8.7%)
Any cardiac disease**	11 (8.7%)
Chronic kidney disease	9 (7.1%)
Type of chronic therapy, *n* (%):	
Statins	19 (15.7%)
Low-dose aspirin	15 (11.9%)
ARBs	15 (11.9%)

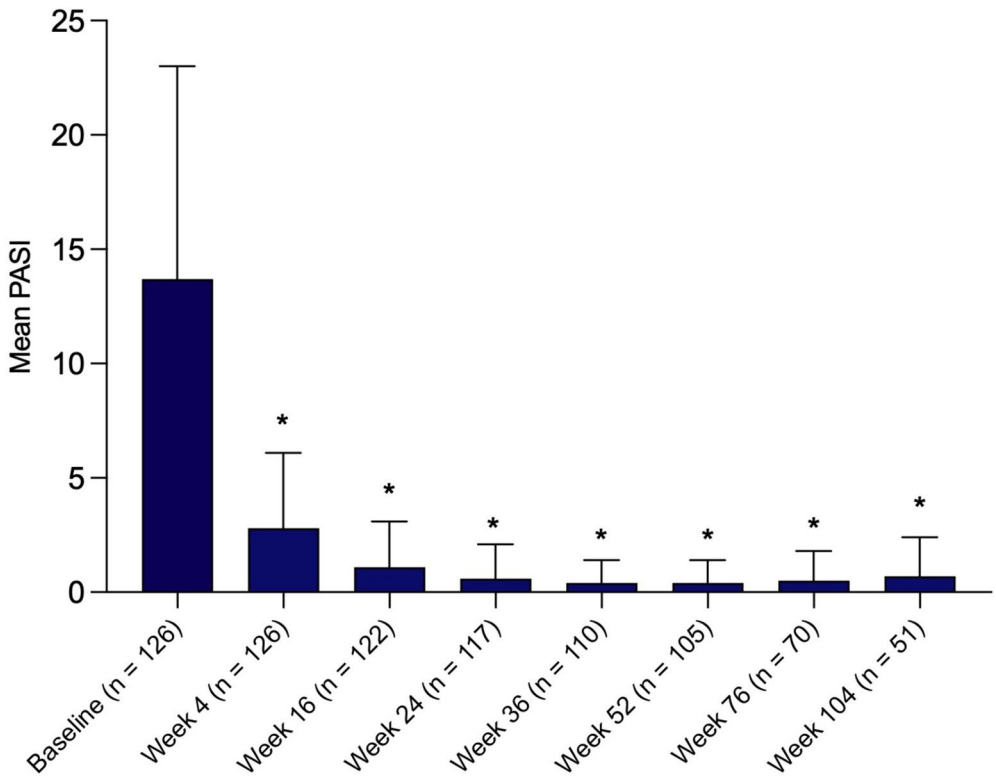
Table 1 continued

Study population	
Metformin	15 (11.9%)
Beta-blockers	14 (11.1%)
Proton pump inhibitors	13 (10.3%)
ACE inhibitors	12 (9.5%)
Calcium-channel blockers	10 (7.9%)
Inhalator corticosteroids	7 (5.5%)
GLP1-RA	6 (4.8%)
Biologics failure, *n* (%):	
Naive	41 (32.5%)
1 failure	52 (41.3%)
2 failures	12 (9.5%)
3+ failures	21 (16.7%)
Failures per patient, *n* ± SD:	1.7 (± 1.2)
Previous biologics, *n* (%):	
Adalimumab	62 (49.2%)
Secukinumab	21 (16.7%)
Guselkumab	17 (13.5%)
Ixekizumab	16 (12.5%)
Ustekinumab	9 (7.1%)
Certolizumab	9 (7.1%)
Etanercept	7 (5.5%)
Risankizumab	5 (3.9%)
Brodalumab	2 (1.6%)
Upadacitinib	2 (1.6%)
Golimumab	1 (0.8%)
Infliximab	1 (0.8%)
Tildrakizumab	1 (0.8%)

ADHD anxious–depressive syndrome, *SD* standard deviation, *IQR* interquartile range, *ACE* angiotensin converting enzyme, *ARB* angiotensin-receptor blocker, *GLP1-RA* glucagone-like peptide-1 receptor agonist

[*] Including bipolar disorder

[**] Including ischemic heart disease, atrial fibrillation, atrial flutter, heart failure



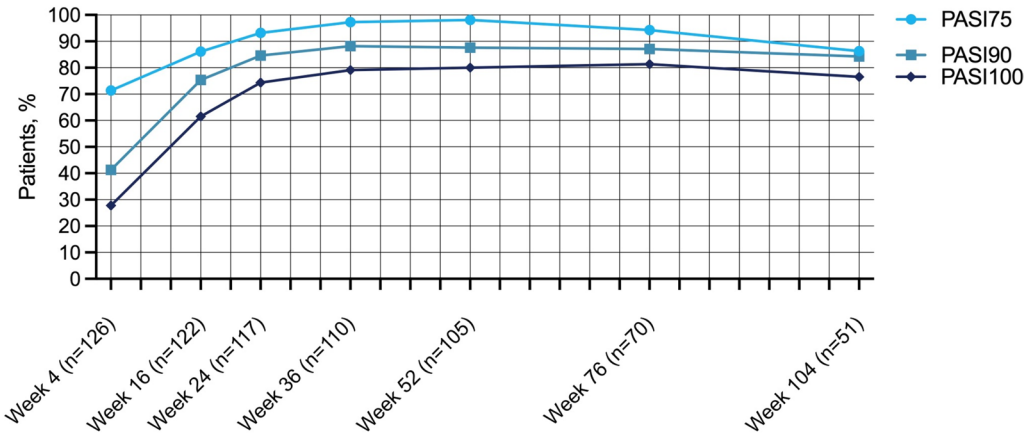
	Baseline (n = 126)	Week 4 (n = 126)	Week 16 (n = 122)	Week 24 (n = 117)	Week 36 (n = 110)	Week 52 (n = 105)	Week 76 (n = 70)	Week 104 (n = 51)
Mean PASI ± SD	13.7 ± 9.3	2.8 ± 3.3	1.1 ± 2.0	0.6 ± 1.5	0.4 ± 1.0	0.4 ± 1.0	0.5 ± 1.3	0.7 ± 1.7
p	NA	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001

Fig. 1 Share of patients achieving PASI75, PASI90, and PASI100 responses over time (the exact number of evaluable patients at each time point is reported on the *x*-axis and in the data table below)

82.5–100) persistence at 720 days. In contrast, bio-experienced patients showed a gradual and significant decline in treatment retention, dropping to 64.0% (95% CI 53.1–77.2) at the 2-year mark.

Safety and Discontinuations

Over the 2-year observation period, a total of 29 clinically significant TEAEs were recorded, corresponding to an incidence rate of 16.8 per 100 patient-years (Table 4). Consistent with the known safety profile of dual IL-17A/F inhibitors, the most frequently reported TEAE was candidiasis, occurring in 14 patients (11.1%; 8.1 per 100 patient-years). The majority of these cases manifested as oral candidiasis ($n = 12$, 9.5%; 6.9 per 100 patient-years), with isolated cases of axillary ($n = 1$, 0.8%; 0.6 per 100 patient-years) and vaginal ($n = 1$,



	Week 4 (n = 126)	Week 16 (n = 122)	Week 24 (n = 117)	Week 36 (n = 110)	Week 52 (n = 105)	Week 76 (n = 70)	Week 104 (n = 51)
PASI 75	71,4%	86,1%	93,2%	97,3%	98,1%	94,3%	86,3%
PASI 90	41,3%	75,4%	84,6%	88,2%	87,6%	87,1%	84,3%
PASI 100	27,8%	61,5%	74,4%	79,1%	80,0%	81,4%	76,5%

Fig. 2 Mean ± SD PASI scores at several time-points over the follow up period. *Statistically significant ($p < 0.05$) change in PASI between baseline and each time point (the exact number of evaluable patients at each time point is reported on the *x*-axis and in the data table below)

0.8%; 0.6 per 100 patient-years) involvement. The second most common adverse event was eczema, reported in 10 patients (7.9%; 5.8 per 100 patient-years). Other non-serious TEAEs included upper respiratory tract infections, diarrhea, and urticaria (each occurring in 2 patients, 1.6%; 1.2 per 100 patient-years). Isolated occurrences of more severe or distinct events were also documented, specifically urosepsis, pneumonia, and mood alteration (each $n = 1$, 0.8%; 0.6 per 100 patient-years).

During the follow-up, 28 patients (22.2%) discontinued bimekizumab treatment. The primary reason for treatment withdrawal was the occurrence of adverse events, which accounted for discontinuations in 17 patients (13.5%). Secondary inefficacy was the underlying cause for 11 discontinuations (8.7%). Among these, 6 patients (4.8%) discontinued owing to a failure to control cutaneous symptoms, while 4 patients (3.2%) discontinued owing to inadequate control of joint symptoms. Additionally, one patient (0.8%) voluntarily discontinued the treatment for personal reasons.

DISCUSSION

This retrospective, real-world study confirms the rapid and sustained effectiveness of bimekizumab in a predominantly bio-experienced cohort of patients with moderate-to-severe plaque psoriasis. Our findings demonstrate that the clinical responses observed in the phase 3 clinical trials BE VIVID, BE READY, and BE SURE translate effectively into routine clinical practice, maintaining high rates of complete skin clearance up to 2 years.

Table 2 Comparison of baseline characteristics of patients reaching PASI100 at week 16 and 52 by multivariate logistic regression of baseline characteristics associated with these outcomes

	PASI100 at week 16					PASI100 at week 52				
	Univariate analysis			Multivariate analysis		Univariate analysis			Multivariate analysis	
Variable	Yes ($n = 75$)	No ($n = 47$)	p	OR (95% CI)	p	Yes ($n = 84$)	No ($n = 21$)	p	OR (95% CI)	p
Sex (Male), n (%)	44 (58.7%)	31 (66.0%)	0.539	0.72 (0.29–1.72)	0.466	50 (59.5%)	15 (71.4%)	0.451	0.55 (0.16–1.68)	0.297
Age, median [IQR]	49.00 [40.50, 59.00]	54.00 [41.00, 62.50]	0.179	0.98 (0.95–1.01)	0.265	49.00 [38.50, 58.25]	53.00 [40.00, 62.00]	0.509	0.98 (0.95–1.02)	0.393
BMI, median [IQR]	26.30 [23.57, 30.50]	27.00 [24.81, 30.70]	0.540	1.01 (0.93–1.10)	0.901	26.20 [23.49, 30.13]	27.53 [25.80, 30.70]	0.149	0.95 (0.86–1.06)	0.331
Disease duration, median [IQR]	13.00 [6.00, 21.00]	11.00 [6.00, 19.50]	0.918			12.00 [6.00, 19.00]	11.00 [7.00, 25.00]	0.569		
Psoriasis family history	26 (34.7%)	15 (31.9%)	0.907			27 (32.1%)	10 (47.6%)	0.283		
Bio-naive status	26 (34.7%)	15 (31.9%)	0.907	1.14 (0.45–3.01)	0.789	29 (34.5%)	9 (42.9%)	0.648	0.84 (0.27–2.74)	0.762
Number of biologics failures, median [IQR]	1.00 [0.00, 1.00]	1.00 [0.00, 2.00]	0.285			1.00 [0.00, 1.00]	1.00 [0.00, 3.00]	0.503		
Baseline PASI, median [IQR]	10.20 [8.00, 14.45]	12.00 [9.00, 17.50]	0.192	0.97 (0.92–1.01)	0.153	10.95 [8.00, 15.05]	12.00 [9.00, 24.00]	0.254	0.97 (0.92–1.03)	0.330
Scalp involvement, n (%)	28 (37.3%)	24 (51.1%)	0.192			36 (42.9%)	7 (33.3%)	0.585		
Palmo-plantar involvement, n (%)	11 (14.7%)	13 (27.7%)	0.128	0.33 (0.12–0.86)	**0.024**	8 (9.5%)	8 (38.1%)	**0.004**	0.16 (0.05–0.51)	**0.002**
Genital involvement, n (%)	28 (37.3%)	12 (25.5%)	0.249			33 (39.3%)	7 (33.3%)	0.802		
Nail involvement, n (%)	20 (26.7%)	26 (55.3%)	**0.003**	0.26 (0.11–0.58)	**0.001**	29 (34.5%)	11 (52.4%)	0.209		

Table 2 continued

Variable	PASI100 at week 16					PASI100 at week 52				
	Univariate analysis			Multivariate analysis		Univariate analysis			Multivariate analysis	
	Yes ($n = 75$)	No ($n = 47$)	p	OR (95% CI)	p	Yes ($n = 84$)	No ($n = 21$)	p	OR (95% CI)	p
Psoriatic arthritis, n (%)	20 (26.7%)	13 (27.7%)	1.000			20 (23.8%)	7 (33.3%)	0.539		
Arterial hypertension, n (%)	23 (30.7%)	16 (34.0%)	0.850			26 (31.0%)	8 (38.1%)	0.715		
Diabetes, n (%)	12 (16.0%)	4 (8.5%)	0.359			12 (14.3%)	2 (9.5%)	0.830		
CKD, n (%)	6 (8.0%)	2 (4.3%)	0.662			5 (6.0%)	2 (9.5%)	0.922		
Any psychiatric disorder*, n (%)	8 (10.7%)	5 (10.6%)	1.000			7 (8.3%)	4 (19.0%)	0.300		
Asthma/allergic rhinitis, n (%)	6 (8.0%)	5 (10.6%)	0.865			7 (8.3%)	2 (9.5%)	1.000		
Any cardiac disease**, n (%)	4 (5.3%)	6 (12.8%)	0.264			7 (8.3%)	1 (4.8%)	0.927		
Dyslipidemia, n (%)	8 (10.7%)	8 (17.0%)	0.462			9 (10.7%)	3 (14.3%)	0.939		
Statin, n (%)	8 (10.7%)	10 (21.3%)	0.178			11 (13.1%)	3 (14.3%)	1.000		
ACEi, n (%)	7 (9.3%)	5 (10.6%)	1.000			7 (8.3%)	5 (23.8%)	0.107	0.35 (0.09–1.35)	0.124
ARBs, n (%)	8 (10.7%)	6 (12.8%)	0.950			8 (9.5%)	3 (14.3%)	0.811		
Metformin, n (%)	11 (14.7%)	4 (8.5%)	0.469			11 (13.1%)	2 (9.5%)	0.941		
GLP1-RA, n (%)	4 (5.3%)	2 (4.3%)	1.000			4 (4.8%)	1 (4.8%)	1.000		
PPI, n (%)	4 (5.3%)	8 (17.0%)	0.072	0.19 (0.04–0.75)	**0.017**	7 (8.3%)	1 (4.8%)	0.927		
Beta blocker, n (%)	8 (10.7%)	4 (8.5%)	0.939			10 (11.9%)	0 (0.0%)	0.213		
Inhalator corticosteroid, n (%)	4 (5.3%)	3 (6.4%)	1.000			4 (4.8%)	1 (4.8%)	1.000		

Table 2 continued

Variable	PASI100 at week 16					PASI100 at week 52			
	Univariate analysis			Multivariate analysis		Univariate analysis		Multivariate analysis	
	Yes ($n = 75$)	No ($n = 47$)	p	OR (95% CI)	p	Yes ($n = 84$)	No ($n = 21$)	p	OR (95% CI)	p
Calcium channel blocker, n (%)	6 (8.0%)	4 (8.5%)	1.000			7 (8.3%)	2 (9.5%)	1.000		
Low dose aspirin, n (%)	6 (8.0%)	8 (17.0%)	0.219			9 (10.7%)	3 (14.3%)	0.939		

SD standard deviation, *IQR* interquartile range, *BMI* body mass index, *CKD* chronic kidney disease, *ACE* angiotensin converting enzyme, *ARB* angiotensin-receptor blocker, *GLP1-RA* glucagone-like peptide-1 receptor agonist, *PPI* proton pump inhibitors

*Including bipolar disorder, ADHD, anxious–depressive syndrome

**Including ischemic heart disease, atrial fibrillation, atrial flutter, heart failure

P-values in bold denote statistical significance (p 0.05)

In our cohort, 61.5% of patients achieved PASI100 at week 16. This aligns closely with the week 16 PASI100 rates reported in the pivotal trials, which ranged from 59% to 68% [4–6], and in other real-world experiences [20]. Notably, this high level of effectiveness was achieved despite our population being highly refractory; over two-thirds of the patients had failed at least one previous biologic, and the mean psoriasis duration was nearly 15 years. Furthermore, the response deepened over time, with 80.0% of patients achieving PASI100 at week 52.

The multivariable logistic regression provided critical insights into the predictors of complete clearance. Involvement of difficult-to-treat areas—specifically the palmo-plantar region and nails—acted as significant negative predictors for achieving early PASI100 (week 16). Palmo-plantar involvement remained a strong negative predictor even at week 52. These anatomical sites are notoriously recalcitrant to treatment [21] owing to thicker stratum corneum and reduced vascularization that may limit drug penetration, and owing to a unique immunological microenvironment which seems to be less IL-17-dependent and driven predominantly by Th1 pathways and interferon (IFN)-γ axis [22]. Nevertheless, while palmo-plantar involvement delayed or reduced the likelihood of absolute clearance, the overall PASI reduction in our cohort remained excellent and the efficacy of bimekizumab on the palmo-plantar domain was demonstrated both in clinical trials [23] and in real-world studies [24].

Interestingly, our week-16 multivariable model identified the concomitant use of PPIs as an independent negative predictor for achieving PASI100. While this association lost its statistical significance at week 52, the early blunting of efficacy is noteworthy. No study has, to our knowledge, evidenced an association between PPI use and PASI outcomes, however a recent cohort study on 36,129 patients found PPIs use to be independently associated with a higher risk of treatment discontinuation [25]. A possible mechanistic rationale involves the gut–skin axis; gastric acid suppression by PPIs can alter the gut microbiota and deplete short-chain fatty acid-producing bacteria, which are essential for maintaining systemic immune homeostasis [26–28].

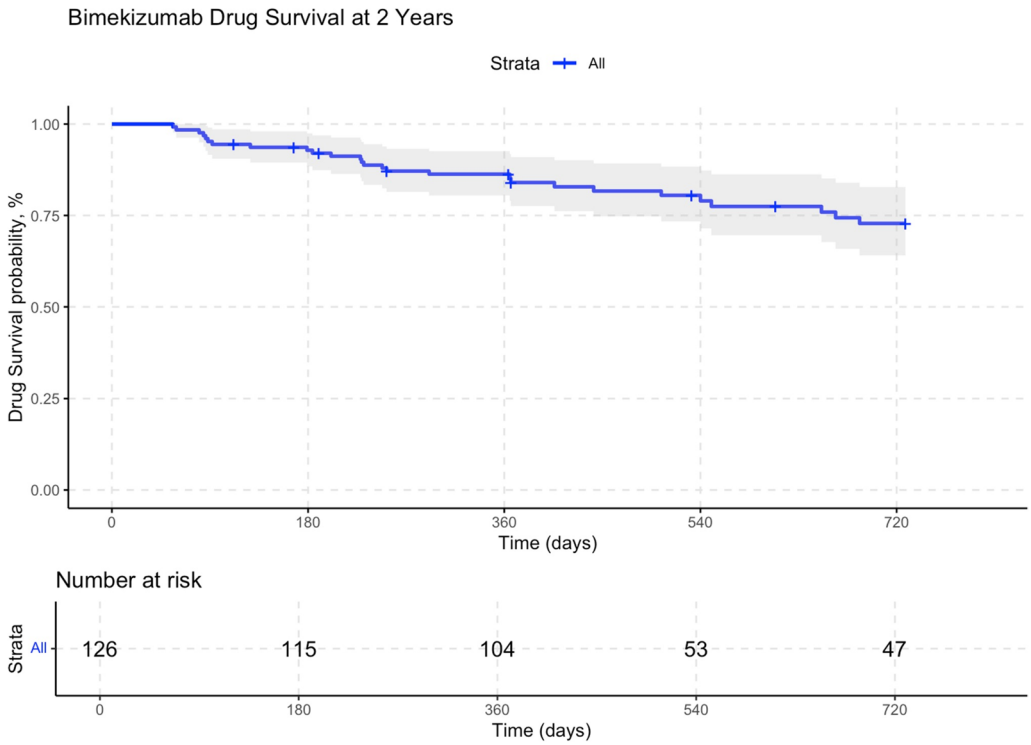


Fig. 3 Overall crude drug survival over 2 years

However, given the small number of patients receiving PPIs in our cohort and the transient nature of this association, this mechanistic link remains strictly speculative. Therefore, the early negative impact of PPIs on complete clearance should be interpreted cautiously as a hypothesis-generating finding, which requires confirmation in larger, adequately powered cohorts.

In the present study, penalized multivariable analysis identified baseline nail involvement as an independent negative predictor for achieving PASI100 at week 16. This aligns with previous evidence characterizing nail psoriasis as a marker of refractory disease. Retrospective analyses have previously reported nail involvement as a negative prognostic factor for clinical response during biological therapy [29]. Furthermore, large real-world cohorts, such as the BADBIR [21] and PSOHO(2) registries, have confirmed that nail involvement significantly decreases the probability of achieving absolute skin clearance. Within the specific context of bimekizumab, we previously demonstrated that the presence of nail psoriasis negatively impacts

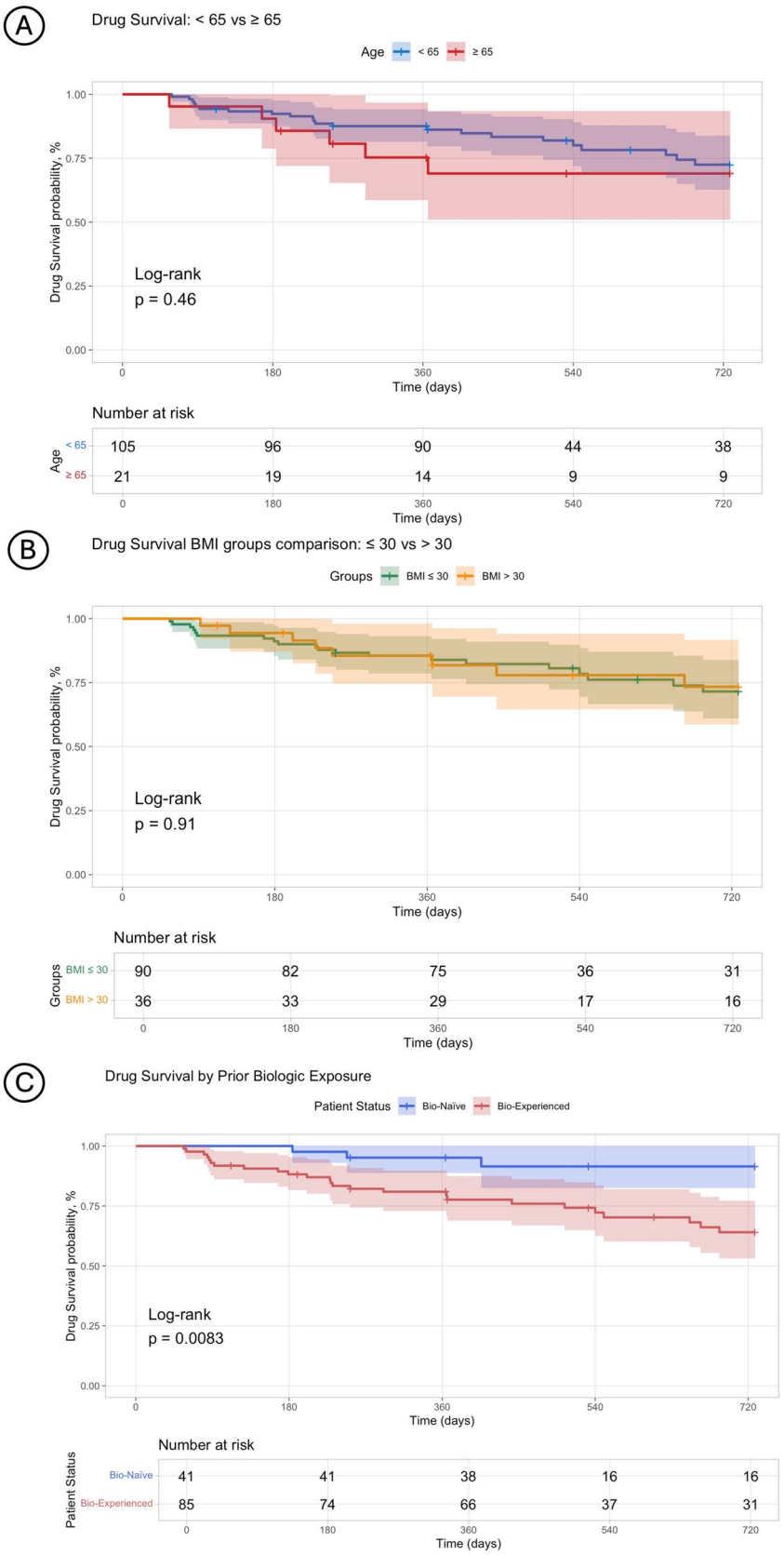
the achievement of an early super response [9]. Notably, nail involvement was no longer a significant negative predictor in our 52-week model. This temporal difference suggests that, while nail disease may delay the initial clearance of cutaneous lesions, sustained dual IL-17A/F inhibition can overcome this clinical resistance over time. Consequently, nail involvement appears to postpone, rather than prevent, the achievement of PASI100 during long-term treatment.

Regarding treatment persistence, our cohort demonstrated a 2-year overall drug survival of 72.2%. Recently, a large Italian multicenter study by De Luca et al. evaluated the 2-year effectiveness, safety, and drug survival of bimekizumab, reporting a higher overall drug survival rate of 82.4% at 24 months. The discrepancy between these survival rates can likely be attributed to distinct baseline characteristics between the two cohorts. Specifically, our study population presented with a notably higher burden of refractory disease. In our cohort, 67.5% of patients were bio-experienced, compared with 52.5% in the De Luca et al. study. Furthermore, the prevalence of concomitant psoriatic arthritis (PsA) was considerably higher in our sample (26.2%) than in the De Luca et al. cohort (15.7%). As PsA and multiple prior biologic failures are well-known factors that can complicate disease management and increase the likelihood of treatment switching [17, 30], these baseline differences likely account for the slightly lower overall persistence observed in our study.

Furthermore, our results were comparable to those reported by Schwarz et al. [17], who described a drug survival of 83.0% and 73.0% at 1 and 2 years, respectively, in a subgroup of bio-experienced patients treated with bimekizumab, strengthening the hypothesis that a history of prior biologic failures may negatively impact treatment persistence.

Building on this observation, a novel finding of our analysis is the relevant impact of prior biologic exposure on long-term drug survival. While De Luca et al. [16] found that biologic-naïve status was not significantly associated with treatment discontinuation in their multivariable analysis, our Kaplan–Meier analysis yielded opposite results: biologic-naïve patients exhibited a 2-year drug survival of 91.5%, whereas bio-experienced patients demonstrated a significantly lower retention rate of 64.0% ($p = 0.0083$). Interestingly, our findings align closely with another recent 104-week real-world study by Takahashi et al. in a Japanese cohort [15]. The authors of the study reported that, while both biologic-naïve and bio-experienced patients achieved rapid early clearance, the achievement rates of PASI90 and PASI100 were mostly sustained through week 104 in biologic-naïve patients, whereas they showed a slight reduction in bio-experienced patients during the later phases of treatment (after week 68 or 92). The waning of long-term clinical response in multi-failure patients observed by Takahashi et al. likely translates into the higher discontinuation rates (and, consequently, the lower drug survival of 64.0%) seen in the bio-experienced arm of our cohort. This suggests that, while bimekizumab is highly effective as a rescue therapy, biologic-naïve patients may be the most suitable candidates for maintaining uninterrupted, long-term remission. However, these findings should be interpreted with caution. The small sample size and the low number of discontinuation events precluded the performance of a multivariable survival analysis (e.g., Cox regression), thereby limiting the interpretation regarding the independent impact of each baseline variable on the overall risk of discontinuation.

A pivotal finding of our analysis is the consistent efficacy and drug survival of bimekizumab across different BMI and age categories. Historically, obesity has been a well-documented negative predictor for biologic response [31] and drug survival in psoriasis [30], primarily owing to altered pharmacokinetics and a higher pro-inflammatory state [32, 33]. However, our data revealed no significant difference in 2-year drug survival between obese


A
Drug Survival: < 65 vs ≥ 65
Age < 65 ≥ 65
Drug Survival probability, %
1.00
0.75
0.50
0.25
0.00
Log-rank
p = 0.46
0
180
360
540
720
Time (days)
Number at risk
Age
< 65 105 96 90 44 38
≥ 65 21 19 14 9 9
0
180
360
540
720
Time (days)
B
Drug Survival BMI groups comparison: ≤ 30 vs > 30
Groups BMI ≤ 30 BMI > 30
Drug Survival probability, %
1.00
0.75
0.50
0.25
0.00
Log-rank
p = 0.91
0
180
360
540
720
Time (days)
Number at risk
Groups
BMI ≤ 30 90 82 75 36 31
BMI > 30 36 33 29 17 16
0
180
360
540
720
Time (days)
C
Drug Survival by Prior Biologic Exposure
Patient Status Bio-Naïve Bio-Experienced
Drug Survival probability, %
1.00
0.75
0.50
0.25
0.00
Log-rank
p = 0.0083
0
180
360
540
720
Time (days)
Number at risk
Patient Status
Bio-Naïve 41 41 38 16 16
Bio-Experienced 85 74 66 37 31
0
180
360
540
720
Time (days)

◂**Fig. 4** Crude drug survival over 2 years, subgroup analysis: **A** patients aged < 65 years and > 65 years; **B** patients with BMI < 30 and > 30; **C** bio-naïve versus bio-experienced

(BMI > 30) and non-obese patients. Similarly, the multivariable models confirmed that BMI did not preclude the achievement of PASI100, providing new evidence on the unaltered effectiveness of bimekizumab in this special population [10]. Furthermore, the comparable drug survival between patients aged < 65 and ≥ 65 years supports the use of bimekizumab as a durable option in the older population, a group often underrepresented in clinical trials.

Regarding safety and treatment persistence, the adverse event profile observed in our cohort was consistent with the established safety profile of bimekizumab. Overall, clinically significant TEAEs were recorded in 23.0% of patients, corresponding to an incidence rate of 16.8 per 100 patient-years. The most frequently reported TEAE was candidiasis (11.1%; 8.1 per 100 patient-years), which predominantly involved the oral mucosa (9.5%) and presented with a median onset at week 20.5 (IQR: 14.5–46.0). This is a well-documented, anticipated class effect of IL-17 inhibitors, as the dual inhibition of IL-17A and IL-17F profoundly impacts mucosal defense mechanisms against fungal infections [34]. However, these cases are typically mild-to-moderate and manageable in routine clinical practice. Eczematous eruptions represented the second most common TEAE, occurring in 7.9% of the cohort (5.8 per 100 patient-years) with a median onset at week 22.0 (IQR 16.3–26.3). Previous real-world experiences reported similar frequencies, with treatment-associated eczemas occurring in 4–7% of patients [35, 36].

Overall, treatment discontinuations occurred in 22.2% of patients over the 2-year period. The primary reasons for drug withdrawal were adverse events (13.5%) and secondary inefficacy (8.7%). Notably, discontinuation due to secondary inefficacy was driven by a failure to control cutaneous symptoms in 4.8% of cases, and a failure to adequately manage concomitant joint symptoms in 3.2% of cases, further highlighting the burden of psoriatic arthritis in our population.

Limitations

Our study has limitations inherent to its retrospective nature, including the lack of a control group. Additionally, the sample size, while sufficient for the primary overall analyses, resulted in smaller subgroups (e.g., at week 104 or within specific comorbidity strata), which may limit the statistical power to detect minor differences. Of note, the reduced sample size at week 104 reflects the staggered initiation of treatment in routine practice rather than loss to follow-up.

Finally, safety data and specific reasons for discontinuation (e.g., primary failure versus adverse events such as oral candidiasis) were not the primary focus of this specific survival analysis but remain critical factors in overall clinical decision-making.

Table 3 Drug survival in the study population and comparison between age and BMI groups and bio-naive status

Days	Overall, % (95% CI)	Age < 65, % (95% CI)	Age > 65, % (95% CI)	BMI = < 30, % (95% CI)	BMI > 30, % (95% CI)	Bio-naïve, % (95% CI)	Bio-experienced, % (95% CI)
180	92.0% (87.4–96.9)	92.4% (87.4–97.6)	90.5% (78.8–100)	91.1% (85.4–97.2)	94.4% (87.1–100)	100.0% (100–100)	88.2% (81.6–95.3)
360	84.4% (78.2–91.2)	86.2% (79.6–93.2)	75.3% (58.6–96.8)	83.9% (76.4–92.1)	85.5% (74.5–98.1)	95.1% (88.8–100)	79.3% (70.9–88.6)
540	78.3% (70.8–86.7)	80.1% (71.9–89.1)	69.0% (51.0–93.5)	78.4% (69.4–88.5)	77.9% (64.5–94.1)	91.5% (82.5–100)	72.2% (62.5–83.5)
720	72.2% (63.5–82.2)	72.5% (62.7–83.8)	69.0% (51.0–93.5)	71.5% (60.9–83.9)	73.3% (58.7–91.6)	91.5% (82.5–100)	64.0% (53.1–77.2)

Table 4 Clinically significant treatment emergent adverse events observed during the treatment period and causes of discontinuation

	TEAEs, *n* (%):	TEAEs per 100 patient-years
Total:	29 (23.0%)	16.8
Candidiasis, *n* (%)	14 (11.1%)	8.1
Oral	12 (9.5%)	6.9
Axillary	1 (0.8%)	0.6
Vaginal	1 (0.8%)	0.6
Eczema, *n* (%)	10 (7.9%)	5.8
Upper airway tract infection, *n* (%)	2 (1.6%)	1.2
Diarrhea	2 (1.6%)	1.2
Urticaria	2 (1.6%)	1.2
Urosepsis	1 (0.8%)	0.6
Pneumonia	1 (0.8%)	0.6
Mood alteration, *n* (%)	1 (0.8%)	0.6
Discontinuations:		
Total, *n* (%)	28 (22.2%)	
Adverse events, *n* (%):	17 (13.5%)	
Secondary inefficacy, *n* (%):	11 (8.7%)	
Failure to control cutaneous symptoms	6 (4.8%)	
Failure to control joint symptoms	4 (3.2%)	
Voluntary discontinuation:	1 (0.8%)	

TEAEs treatment emergent adverse events, *SD* standard deviation

CONCLUSIONS

This 2-year real-world analysis reinforces the position of bimekizumab as a highly effective and durable therapeutic option for moderate-to-severe plaque psoriasis. The dual IL-17A/F blockade provides sustained rates of complete clearance, demonstrating a robust drug survival profile that is not negatively impacted by challenging patient characteristics such as obesity and advanced age. Although a history of multiple biologic failures is associated with lower long-term treatment retention compared with biologic-naïve status, high levels of absolute skin clearance remain consistently attainable, confirming the value of bimekizumab even in heavily pretreated populations.

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Data Availability. The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Conflict of interest. Zeno Fratton, Stefano Bighetti, Luca Bettolini, Marina Venturini, Mariateresa Rossi, Andrea Carugno, Nicola Zerbinati, and Giuseppe Stinco declare that they have no competing interests. Enzo Errichetti and Mariateresa Rossi are Editorial Board members of *Dermatology and Therapy*. Enzo Errichetti and Mariateresa Rossi were not involved in the selection of peer reviewers for the manuscript nor any of the subsequent editorial decisions.

Ethical Approval. The study was conducted in accordance with the ethical standards established by the 1964 Declaration of Helsinki and its later amendments. Ethical approval was obtained from the local Ethics Committee (Comitato Etico Territoriale Lombardia 6, protocol 4710). Written informed consent to participate in the study, for the use of medical records for research purposes, and for the publication of non-identifying data was obtained from all individual participants included in the study.

REFERENCES

1. Armstrong AW, Blauvelt A, Callis Duffin K, Huang YH, Savage LJ, Guo L, et al. Psoriasis. Nat Rev Dis Primers. 2025;11(1):45. https://doi.org/10.1038/s41572-025-00630-5.

2. Armstrong AW, Riedl E, Brunner PM, Piaserico S, Visser WI, Haustrup N, et al. Identifying predictors of PASI100 responses up to month 12 in patients with moderate-to-severe psoriasis receiving biologics in the Psoriasis Study of Health Outcomes (PSoHO). Acta Derm Venereol. 2024;104:adv40556. https://doi.org/10.2340/actadv.v104.40556.

3. Greer ME, Moran SK, Feldman SR. Bimekizumab-bkzx for the treatment of plaque psoriasis: a drug review. Ann Pharmacother. 2025;59(6):577–84. https://doi.org/10.1177/10600280241288553.

4. Warren RB, Blauvelt A, Bagel J, Papp KA, Yamauchi P, Armstrong A, et al. Bimekizumab versus adalimumab in plaque psoriasis. N Engl J Med. 2021;385(2):130–41. https://doi.org/10.1056/NEJMoa2102388.

5. Reich K, Papp KA, Blauvelt A, Langley RG, Armstrong A, Warren RB, et al. Bimekizumab versus ustekinumab for the treatment of moderate to severe plaque psoriasis (BE VIVID): efficacy and safety from a 52-week, multicentre, double-blind, active comparator and placebo controlled phase 3 trial. Lancet. 2021;397(10273):487–98. https://doi.org/10.1016/S0140-6736(21)00125-2.

6. Reich K, Warren RB, Lebwohl M, Gooderham M, Strober B, Langley RG, et al. Bimekizumab versus secukinumab in plaque psoriasis. N Engl J Med. 2021;385(2):142–52. https://doi.org/10.1056/NEJMoa2102383.

7. Strober B, Tada Y, Mrowietz U, Lebwohl M, Foley P, Langley RG, et al. Bimekizumab maintenance of response through 3 years in patients with moderate-to-severe plaque psoriasis: results from the BE BRIGHT open-label extension trial. Br J Dermatol. 2023;188(6):749–59. https://doi.org/10.1093/bjd/ljad035.

8. Gargiulo L, Narcisi A, Ibba L, Balato A, Bianchi L, Brianti P, et al. Effectiveness and safety of bimekizumab for the treatment of plaque psoriasis: a real-life multicenter study-IL PSO (Italian landscape psoriasis). Front Med. 2023;10:1243843. https://doi.org/10.3389/fmed.2023.1243843.

9. Fratton Z, Bighetti S, Bettolini L, Maione V, Arisi M, Buligan C, et al. Real-world experience of bimekizumab in a cohort of 109 patients over 48 weeks and identification of predictive factors for an early super response and risk of adverse events. Psoriasis: Targets Ther. 2025;15:145–58. https://doi.org/10.2147/PTT.S514249.

10. Fratton Z, Maione V, Bighetti S, Bettolini L, Stinco G, Errichetti E. Real-life experience of bimekizumab in 27 obese patients with plaque-type psoriasis: a 24-week multicenter retrospective study. Dermatol Pract Concept. 2025. https://doi.org/10.5826/dpc.1501a4893.

11. Fratton Z, Balato A, Bighetti S, Bettolini L, Maione V, Calzavara-Pinton P, et al. Real-world experience using Bimekizumab in a patient cohort with plaque-type psoriasis and chronic kidney disease: a 48-week retrospective multicentre study. Int J Dermatol. 2025;64(6):1095–7. https://doi.org/10.1111/ijd.17657.

12. Orsini D, Megna M, Assorgi C, Balato A, Balestri R, Bernardini N, et al. Efficacy and safety of bimekizumab in elderly patients: real-world multicenter retrospective study—IL PSO (Italian landscape psoriasis). J Dermatol Treat. 2024;35(1):2393376. https://doi.org/10.1080/09546634.2024.2393376.

13. Megna M, Battista T, Potestio L, Ruggiero A, Ventura V, Fabbrocini G, et al. A case of erythrodermic psoriasis rapidly and successfully treated with bimekizumab. J Cosmet Dermatol. 2023;22(3):1146–8. https://doi.org/10.1111/jocd.15543.

14. Orsini D, Malagoli P, Balato A, Bianchi L, Brianti P, Buononato D, et al. Bimekizumab for the treatment of plaque psoriasis with involvement of genitalia: a 16-week multicenter real-world experience—IL PSO (Italian Landscape Psoriasis). Dermatol Pract Concept. 2024;14(2):e2024052. https://doi.org/10.5826/dpc.1402a52.

15. Takahashi Y, Hagino T, Saeki H, Fujimoto E, Kanda N. A 104-week real-world outcome of bimekizumab treatment for psoriasis: biologic-naïve versus-experienced patients. J Dermatol. 2025;52(12):1856–63. https://doi.org/10.1111/1346-8138.17962.

16. De Luca E, Dattola A, Artosi F, Bellinato F, Bianchi L, Burlando M, et al. Long-term effectiveness of bimekizumab in plaque psoriasis: 2-year drug survival from a real-life multicentre Italian study.

Clin Exp Dermatol. 2026. https://doi.org/10.1093/ced/llag021.

17. Schwarz CW, Loft N, Bryld LE, Nissen CV, Ajgeiy KK, Bertelsen T, et al. Drug survival of biologics in bionaive and bioexperienced patients with psoriasis. JAMA Dermatol. 2026;162(2):166. https://doi.org/10.1001/jamadermatol.2025.5205.

18. Costanzo A, Malara G, Pelucchi C, Fatiga F, Barbera G, Franchi A, et al. Effectiveness end points in real-world studies on biological therapies in psoriasis: systematic review with focus on drug survival. Dermatology. 2018;234(1–2):1–12. https://doi.org/10.1159/000488586.

19. Gisondi P, Fargnoli MC, Amerio P, Argenziano G, Bardazzi F, Bianchi L, et al. Italian adaptation of EuroGuiDerm guideline on the systemic treatment of chronic plaque psoriasis. Ital J Dermatol Venereol. 2022. https://doi.org/10.23736/S2784-8671.21.07132-2.

20. Esposito M, Gisondi P, Assorgi C, Bellinato F, Brianti P, Burlando M, et al. Super responder profile under bimekizumab treatment in moderate-to-severe psoriasis: a short term real-life observation—IL PSO (Italian Landscape Psoriasis). Clin Drug Investig. 2025;45(6):309–15. https://doi.org/10.1007/s40261-025-01440-z.

21. Warren RB, Marsden A, Tomenson B, Mason KJ, Soliman MM, Burden AD, et al. Identifying demographic, social and clinical predictors of biologic therapy effectiveness in psoriasis: a multicentre longitudinal cohort study. Br J Dermatol. 2019;180(5):1069–76. https://doi.org/10.1111/bjd.16776.

22. Wang CQ, Haxhinasto S, Garcet S, Kunjravia N, Cueto I, Gonzalez J, et al. Comparison of the inflammatory circuits in psoriasis vulgaris, non-pustular palmoplantar psoriasis, and palmoplantar pustular psoriasis. J Investig Dermatol. 2023;143(1):87–97.e14. https://doi.org/10.1016/j.jid.2022.05.1094.

23. Merola JF, Gottlieb AB, Pinter A, Elewski B, Gooderham M, Warren RB, et al. Bimekizumab efficacy in high-impact areas: pooled 2-year analysis in scalp, nail, and palmoplantar psoriasis from phase 3/3b randomized controlled trials. Dermatol Ther (Heidelb). 2024;14(12):3291–306. https://doi.org/10.1007/s13555-024-01295-w.

24. Bianco M, D'Oria F, Ghezzi G, Ibba L, Di Giulio S, Valenti M, et al. Real-life effectiveness and safety of bimekizumab in plaque psoriasis involving difficult-to-treat areas: a 52-week, retrospective real-world, single-center study. J Clin Med. 2025;14(20):7412. https://doi.org/10.3390/jcm14207412.

25. Ouakrat R, Penso L, Jullien D, Sokol H, Sbidian E. Antibiotic use and the persistence of biologic therapies in patients with psoriasis. JAMA Dermatol. 2026;162(1):55. https://doi.org/10.1001/jamadermatol.2025.4427.

26. Zhang J, Zhang C, Zhang Q, Yu L, Chen W, Xue Y, et al. Meta-analysis of the effects of proton pump inhibitors on the human gut microbiota. BMC Microbiol. 2023;23(1):171. https://doi.org/10.1186/s12866-023-02895-w.

27. Chen J, Sun K, Zhang X, Chen X, Chu Y, Geng L, et al. Psoriasis and gut microbes: research advances from mechanism to therapy. Front Microbiol. 2025. https://doi.org/10.3389/fmicb.2025.1711288.

28. Xue M, Deng Q, Deng L, Xun T, Huang T, Zhao J, et al. Alterations of gut microbiota for the onset and treatment of psoriasis: a systematic review. Eur J Pharmacol. 2025;998:177521. https://doi.org/10.1016/j.ejphar.2025.177521.

29. Bardazzi F, Lambertini M, Chessa MA, Magnano M, Patrizi A, Piraccini BM. Nail involvement as a negative prognostic factor in biological therapy for psoriasis: a retrospective study. J Eur Acad Dermatol Venereol. 2017;31(5):843–6. https://doi.org/10.1111/jdv.13979.

30. Motedayen Aval L, Yiu ZZN, Alabas OA, Griffiths CEM, Reynolds NJ, Hampton PJ, et al. Drug survival of IL-23 and IL-17 inhibitors versus other biologics for psoriasis: a British Association of Dermatologists Biologics and Immunomodulators Register cohort study. J Eur Acad Dermatol Venereol. 2025;39(10):1785–95. https://doi.org/10.1111/jdv.20739.

31. Hjort G, Schwarz CW, Skov L, Loft N. Clinical characteristics associated with response to biologics in the treatment of psoriasis. JAMA Dermatol. 2024;160(8):830. https://doi.org/10.1001/jamadermatol.2024.1677.

32. Gisondi P, Bellinato F, Girolomoni G, Albanesi C. Pathogenesis of chronic plaque psoriasis and its intersection with cardio-metabolic comorbidities. Front Pharmacol. 2020. https://doi.org/10.3389/fphar.2020.00117.

33. Gisondi P, Fratton Z, Vighi da Rosa R, Bellini V, Carugno A. Unveiling the IL-17 axis: an immunometabolic bridge between psoriasis and metabolic syndrome. J Dermatol Treat. 2026. https://doi.org/10.1080/09546634.2026.2673285.

34. Tangye SG, Puel A. The Th17/IL-17 axis and host defense against fungal infections. J Allergy Clin Immunol Pract. 2023;11(6):1624–34. https://doi.org/10.1016/j.jaip.2023.04.015.

35. Potestio L, Ruggiero A, Martora F, Megna M. Long-term efficacy and safety of bimekizumab in real-world setting: a 52-week prospective study. Arch Dermatol Res. 2024;317(1):102. https://doi.org/10.1007/s00403-024-03594-w.

36. Caldarola G, De Luca E, Amato S, Belcastro A, Bernardini N, Bianchi L, et al. Predictive factors for eczematous eruptions and candidiasis during anti-interleukin-17 treatment in patients with psoriasis: a multicentre real-life experience in Lazio region, Italy. Clin Exp Dermatol. 2025;50(11):2185–91. https://doi.org/10.1093/ced/llaf271.