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BRIEF REPORT

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Bimekizumab for the treatment of moderate to severe psoriasis: a real-world experience over 52 weeks from two Italian dermatology clinics

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ABSTRACT

Purpose: Psoriasis is a chronic, immune-mediated inflammatory skin condition marked by erythematous, scaly plaques. This retrospective observational study evaluated the long-term efficacy and safety of bimekizumab, a dual IL-17A and IL-17F inhibitor, in treating moderate to severe plaque psoriasis in 56 patients across two dermatology clinics in Italy. **Materials and methods:** Adult participants with a baseline Psoriasis Area and Severity Index (PASI) >10, or <10 with sensitive area involvement, were followed for 16 to 52 weeks. Clinical outcomes were measured by PASI 75, 90, and 100 responses and Dermatology Life Quality Index (DLQI) scores at 4, 16, 36, and 52 weeks. **Results:** At week 16, 97.5% of patients achieved PASI 75, 76.7% reached PASI 90, and 66% attained PASI 100. By week 52, 91.5% achieved PASI 90 and 85.1% reached PASI 100, with 95.7% reporting a Dermatology Life Quality Index (DLQI) score of 0 or 1, indicating minimal impact on daily life. The study found similar efficacy across bio-naïve and bio-experienced groups, and between normal-weight and obese patients, without statistically significant differences. The safety profile was consistent with previous trials, with oral candidiasis as the most frequent adverse event (21%). **Conclusions:** These findings support the efficacy and tolerability of bimekizumab for long-term psoriasis management.

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Psoriasis; PASI; interleukin 17; bimekizumab; DLQI

Introduction

Psoriasis is a chronic immune-mediated inflammatory condition predominantly affecting the skin, characterized by the presence of erythematous, scaly plaques and patches (1). Management of moderate to severe psoriasis includes conventional systemic therapies and biologic agents (1). Notably, several monoclonal antibodies have been developed to target two pivotal cytokines involved in the pathogenesis of psoriasis: interleukin (IL)-23 and IL-17 (2).

The IL-17 cytokine family, which includes isoforms A and F, plays a crucial role in intercellular signaling networks that maintain tissue homeostasis. Dysregulation and overexpression of these cytokines are implicated in various inflammatory diseases, including psoriasis (3). While IL-17A has been the focus of extensive research regarding its role in psoriasis, recent findings indicate that a predominant number of T-cells within psoriatic lesions express IL-17F rather than IL-17A (4). This observation may elucidate the clinical effectiveness of simultaneous blockade of IL-17A and IL-17F, which has shown promising results in patients previously unresponsive to selective anti-IL-17A therapies (5).

IL-17A is the therapeutic target of two biologic agents, secukinumab and ixekizumab, whereas the IL-17A receptor is inhibited by brodalumab (1). The most recent biologic approved for the treatment of moderate to severe psoriasis is bimekizumab, which inhibits both IL-17A and IL-17F isoforms (6). The efficacy of bimekizumab has been substantiated in several Phase III clinical trials, including BE READY, BE VIVID, BE SURE, and BE RADIANT (7–10). Short-term real-world studies have corroborated the findings from these clinical trials (11), yet data concerning medium- to long-term outcomes remain limited (12). This study aims to present the results observed in patients with psoriasis treated with bimekizumab over a 52-week period at two dermatology clinics in Italy.

Method

We conducted a retrospective observational study to evaluate the efficacy and safety of bimekizumab therapy in patients with plaque psoriasis at two dermatology clinics, with a follow-up period ranging from 16 to 52 weeks. Eligible participants included adults with moderate to severe plaque psoriasis, defined by a Psoriasis Area and Severity Index (PASI) score greater than 10, or a PASI score less than 10 accompanied by involvement of sensitive areas such as the palmoplantar region, genital area, scalp, or face. All patients had undergone at least 16 weeks of bimekizumab treatment and had either shown an inadequate response to previous systemic therapies or had contraindications to those treatments, in accordance with Italian clinical guidelines (13). Participants were required to be at least 18 years old, able to comprehend the study requirements, and capable of effective communication with the study investigators. Written informed consent was obtained from all participants before any study procedures.

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Patients were excluded if they had active infections, were pregnant, had a history of tumors.

Before initiating therapy, all patients underwent screening for viral hepatitis B and C, HIV, and latent tuberculosis. Bimekizumab was administered according to the product's summary of characteristics, with two subcutaneous injections of 160 mg each given at weeks 0, 4, 8, 12, and 16, followed by two injections every eight weeks thereafter (14).

Each patient was evaluated at 4-, 16-, 36-, and 52-weeks post-treatment initiation. Data were collected on the achievement of PASI 75, PASI 90, and PASI 100, which correspond to percentage reductions of 75%, 90%, and 100%, respectively, from the baseline psoriasis area and severity index (PASI). Improvement in quality of life was assessed at each follow-up visit using the Dermatology Life Quality Index (DLQI).

We also performed a sub analysis to compare treatment efficacy between bio-naïve and bio-experienced patients, as well as between obese patients (BMI > 30) and those of normal weight. Additionally, adverse events (AEs) were recorded at each visit. Categorical data are presented as absolute frequencies and percentages, while continuous data are expressed as means and standard deviations (SD). We used the Chi-square test to assess statistical differences between naïve and bio-experienced patients and between normal-weight and obese patients, and a p value less than or equal to .05 was considered statistically significant. The Institutional review board approval was exempted as the study protocol did not deviate from standard clinical practice. All patients provided written informed consent for the data collection during routine clinical practice (demographics, clinical scores). The study was performed in accordance with the Helsinki Declaration of 1964 and its later amendments. Data collection and handling complied with applicable laws, regulations, and guidance regarding patient protection, including patient privacy.

Results

Descriptive analysis

A total of 56 patients were analyzed. The demographic characteristics of the study population at baseline are detailed in Table 1, including variables such as gender, body mass index (BMI), locations of difficult-to-treat lesions (e.g., scalp, genital region, palmoplantar region), metabolic comorbidities, and prior treatments with biological systemic therapies.

Table 1. Demographic and clinical characteristics of our cohort at baseline.

Number of patients	56
Male, no (%)	41 (73.2%)
Age, mean (SD), years	51 (16.6)
BMI, mean (SD), kg/m^2	27.7 (5.4)
Obese (BMI ≥30), no. (%)	20 (35.7)
PsA, no. (%)	16 (28.5)
PASI at baseline, mean (SD)	14.4 (10.6)
DLQI at baseline, mean (SD)	8.8 (7.6)
Difficult-to-treat areas, no. (%)	26 (46.4)
Type II diabetes, no. (%)	8 (14.2)
Hypertension, no. (%)	15 (26.7)
Dyslipidemia, no. (%)	14 (25)
Heart disease, no. (%)	8 (14.2)
Bio-experience, no. (%)	39 (69.7)
Previous anti-TNF, no. (%)	22 (39.2)
Previous anti-IL 12/23, no. (%)	9 (16.1)
Previous anti-IL 17, no. (%)	11 (19.6)
Previous anti-IL 23, no. (%)	6 (10.7)
Previous apremilast, no. (%)	6 (10.3)

Note: BMI: body mass index; PsA: psoriatic arthritis; PASI: psoriasis area and severity index; DLQI: dermatology life quality index.

The mean age of the patients in our study was 51 years (SD 16.6), with 41 participants (73.2%) identifying as males. The average body mass index (BMI) was 27.7 kg/m^2 (SD 5.4), and 20 patients (35.7%) were classified as obese. The most common comorbidities observed in the cohort included hypertension (26.7%), dyslipidemia (25%), type II diabetes (14.2%), and heart disease (14.2%). None of the patients tested positive for hepatitis B or C. Two patients tested positive for the TB Gold test but showed no radiological signs of active tuberculosis; following consultation with infectious disease specialists, they received a three-month prophylactic treatment prior to starting bimekizumab.

Among the patients, 16 (28.5%) had a concomitant diagnosis of psoriatic arthritis. Seventeen patients (30.3%) were naïve to biological therapies, while 39 patients (69.7%) had previously received at least one biological treatment (bio-experienced). The mean PASI score at baseline was 14.4 (SD 10.6). Notably, 26 patients (46.4%) presented with lesions in at least one difficult-to-treat area (such as the scalp, face, palms, soles, genital regions, or nails). Severe impairment in quality of life, indicated by a Dermatology Life Quality Index (DLQI) score of ≥10, was reported by 27 patients (48.2%).

Overall treatment efficacy

All 56 patients completed the initial 16 weeks of follow-up. At week 4, 64.2% of patients achieved PASI 75, while 33.9% and 30.3% reached PASI 90 and PASI 100, respectively. By week 16, the proportions of patients achieving PASI 75, PASI 90, and PASI 100 were 97.5%, 76.7%, and 66%, respectively; additionally, 76.6% achieved an absolute PASI score of ≤2. The mean PASI score decreased to 4 (SD 5) at week 4 and further reduced to 0.92 (SD 1.8) by week 16.

Among the 50 patients who completed the 36-week follow-up, 47 (94%) achieved PASI 90, and 42 (84%) achieved PASI 100, with 92% of the sample attaining an absolute PASI score of ≤2. At 52 weeks, 47 patients were evaluated, of whom 43 (91.5%) achieved PASI 90, and 40 (85.1%) achieved complete skin clearance (PASI 100). Notably, 100% of the cohort reached PASI 75, and 46 of 47 patients (97.5%) achieved an absolute PASI score of ≤2. The mean PASI score was 0.37 (SD 0.9) at week 36, further decreasing to 0.27 (SD 0.78) at week 52. The improvement in PASI scores is illustrated in Figure 1.

Improvements in PASI were associated with a concurrent decrease in the mean DLQI throughout the study period, with scores of 1.5 (SD 2.5) at week 4, 0.4 (SD 1.5) at week 16, 0.18 (SD 0.6) at week 36, and 0.1 (SD 0.5) at week 52. At the 52-week mark, 45 patients (95.7%) reported a DLQI score of 0 or 1.

Effectiveness comparison between normal-weight and obese patients

In the subgroup analysis of obese patients at week 36, 88.8% achieved PASI 90 and 77.7% achieved PASI 100, compared to 96.8% and 85.7%, respectively, among normal-weight patients. However, the differences observed in PASI 90 (p = .257) and PASI 100 (p = .312) were not statistically significant. At week 56, normal-weight patients continued to demonstrate higher rates of achieving PASI 90 (96.6% vs. 82.3%, p = .067) and PASI 100 (90% vs. 76.4%, p = .174).

Effectiveness comparison between bio-naïve and bio-experienced patients

Regarding prior exposure to biologics, at week 16, bio-naïve patients achieved PASI 90 at a higher rate (82.3%) compared to

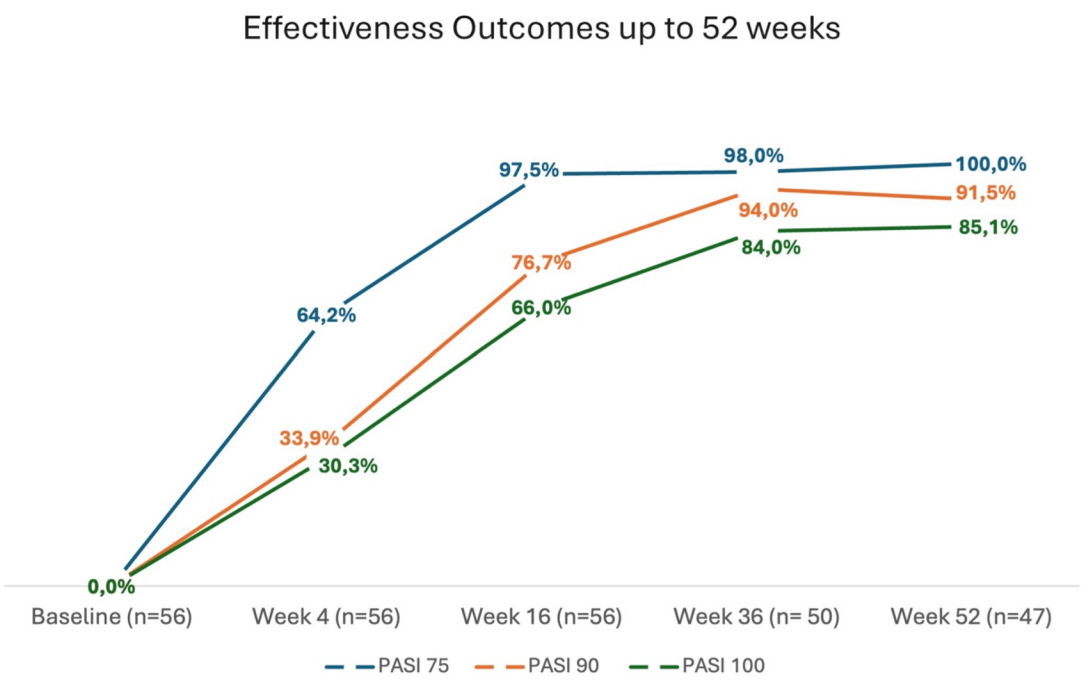

Figure 1. Improvement in PASI score in the category of PASI75, PASI90 and PASI100 responders. PASI: psoriasis area and severity index.

bio-experienced patients (74.4%) ($p = .188$). At week 36, complete skin clearance (PASI 100) was attained by 86% of bio-naïve patients compared to 82.8% of bio-experienced patients ($p = .823$). Similar trends were observed at week 52, with 93.3% of bio-naïve patients achieving PASI 100, compared to 81.2% of bio-experienced patients ($p = .757$).

Safety and tolerability

In terms of safety, the predominant adverse events reported were oral candidiasis, occurring in 12 of 56 patients (21%), and tinea corporis, observed in 3 of 56 patients (5.3%). Most cases of oral candidiasis (11 out of 12, or 91.6%) occurred between weeks 4 and 16, with only two cases persisting to week 36 and one to week 52. No serious adverse events necessitating treatment discontinuation were reported, although one patient withdrew from the study at week 52 due to persistent oral lesions associated with recurrent candidiasis.

Discussion

The real-world data presented in this study on the use of bimekizumab for treating moderate to severe psoriasis reinforces its efficacy and safety profile, extending the findings from clinical trials to a broader patient population. Our results indicate that bimekizumab, which targets both IL-17A and IL-17F isoforms, facilitates substantial and sustained improvements in psoriasis severity and patient quality of life over a 52-week period.

At week 16, 97.5% of patients achieved PASI 75, with significant proportions also achieving PASI 90 (76.7%) and complete skin clearance (PASI 100) (66%). These results compare favorably with previous phase III clinical trials: in particular, higher rates of complete skin clearance (PASI 100) were observed compared to the be radiant (61.7%), be ready (68.2%), be vivid (59%), and be sure (60.8%) trials (7–10). The improvements were either maintained or further enhanced in the extended follow-up. By week 52, 91.5% of patients reached PASI 90, and 85.1% attained complete skin clearance, indicating sustained treatment efficacy. In comparison, the be radiant trial reported that 74.8% of patients achieved PASI 100 at week 48 when receiving bimekizumab every 8 weeks (15). These findings highlight bimekizumab's potential to offer long-term control of psoriasis, which is crucial given the chronic nature of the disease.

Real-world data on bimekizumab therapy remains limited. Gargiulo et al. (11) conducted a 16-week retrospective multicenter study that reported a similar PASI 75 response (97.4% vs. 97.5%) but higher rates of achieving PASI 90 and PASI 100 (89.5% vs. 76.7% and 75.4% vs. 66%) compared to our cohort. We attribute this difference to a higher proportion of bio-experienced patients in our sample (45.5% vs. 69.9%), who typically exhibit a slower response to therapy.

Additionally, a recent study by Sood et al. (12) provided real-world data on 87 patients treated with bimekizumab for up to 52 weeks. Our findings demonstrated superior efficacy outcomes at 52 weeks, with 91.5% achieving PASI 90 compared to 81.6%, and 85.1% achieving PASI 100 versus 70.1%. This discrepancy may be linked to the lower proportion of patients previously exposed to another IL-17 inhibitor in our study (19.6% vs. 47.1%), as previous exposure appears to correlate with reduced effectiveness of subsequent therapies.

Our analysis revealed a differential response between bio-naïve and bio-experienced patients, aligning with findings from previous studies (11,12). However, a prior study (11) showed higher PASI 90 response rates at week 16 for both groups, with 91.1% of bio-naïve and 87.9% of bio-experienced patients reaching this benchmark, compared to 82.3% and 74.4% in our cohort, respectively. This discrepancy is likely due to differences in sample characteristics between the studies, which may have affected the outcomes. Although bio-naïve patients consistently achieved PASI 90 and PASI 100 more frequently than bio-experienced patients at weeks 36 and 52, these differences were not statistically significant. This suggests that bimekizumab could be serve as an effective first-line biological therapy, although it remains beneficial for patients with inadequate responses to prior treatments. Furthermore, our

subgroup analysis indicated that normal-weight patients (BMI < 30) responded more favorably to bimekizumab therapy than obese patients, particularly in achieving PASI 90 and 100, though again without statistically significant differences. The Dermatology Life Quality Index (DLQI) scores demonstrated significant improvement from baseline, reflecting the substantial impact of bimekizumab on enhancing patients' quality of life. At week 52, 95.7% of patients reported DLQI scores of 0 or 1, indicating minimal impact of psoriasis on their daily lives. This outcome underscores the importance of effective psoriasis treatments not only in reducing disease severity but also in improving overall patient well-being.

The safety profile of bimekizumab in our real-world study aligned with previous reports. Oral candidiasis was the most common adverse event, affecting 21% of patients, primarily within the first 16 weeks of treatment. This rate is higher compared to the 9–15% incidence reported in registration trials for bimekizumab (8,9). We attribute this difference to our smaller sample size and the presence of numerous patients with metabolic comorbidities, such as diabetes and obesity, which are known to increase the risk of candidiasis (16). Despite this, the adverse event appeared manageable, with a decline in incidence over time. Only one patient discontinued treatment due to persistent candidiasis by week 52, and no serious adverse events necessitated treatment discontinuation, further supporting the safety and tolerability of bimekizumab for long-term use. Despite these promising findings, this study has limitations. The retrospective design and relatively small sample size may restrict the generalizability of our results. Additionally, as the study was conducted in two dermatology clinics in Italy, it may not fully represent the broader global psoriasis population.

Conclusion

In summary, this study confirms bimekizumab's effectiveness and safety in treating moderate to severe psoriasis over 52 weeks, showing significant improvements in PASI scores and quality of life. High rates of PASI 90 and PASI 100 were achieved across different patient groups, including obese, non-obese, bio-naïve, and bio-experienced individuals. Most adverse events occurred during the first weeks of treatment and were manageable. However, the retrospective design and small sample size may limit the generalizability, highlighting the need for further research to assess long-term outcomes and refine treatment strategies.

Ethics approval

Institutional review board approval was exempted as the study protocol did not deviate from standard clinical practice. All patients received bimekizumab as in good clinical practice, in accordance with guidelines. All included patients had provided written consent for retrospective study of data collected during routine clinical practice (demographics, clinical scores). The study was performed in accordance with the Helsinki Declaration of 1964 and its later amendments. Data collection and handling complied with applicable laws, regulations, and guidance regarding patient protection, including patient privacy.

Authors' contributions

Edoardo Mortato and Fabio Artrosi have given substantial contributions to the conception or the design of the manuscript and to acquisition, analysis and interpretation of the data. All authors contributed equally to drafting the manuscript and read and approved the final version of the manuscript. Elena Campione supervised the paper and approved the final version.

Disclosure statement

L.Bianchi has served as a speaker and as a consultant for AbbVie, Novartis, Janssen-Cilag, Pfizer, UCB, and LeoPharma. E. Campione has served as advisory board member, received fees for lectures and/or research grants by Almirall, Amgen, Abbvie, Bristol Myers Squibb, Incyte, Leo Pharma. The other authors declare no conflicts of interest.

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Data availability statement

The data that support the findings of this study are available on request from the corresponding author, E.C.

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