Journal of Dermatological Treatment

ISSN: 0954-6634 (Print) 1471-1753 (Online) Journal homepage: www.tandfonline.com/journals/ijdt20

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To cite this article: D. Orsini, M. Megna, C. Assorgi, A. Balato, R. Balestri, N. Bernardini, A. Bettacchi, T. Bianchelli, L. Bianchi, G. Buggiani, M. Burlando, AMG. Brunasso, G. Caldarola, N. Cameli, A. Campanati, E. Campione, A. Carugno, K. Chersi, A. Conti, A. Costanzo, E. Cozzani, A. Cuccia, D. D'Amico, G. Dal Bello, E. G. Dall'Olio, P. Dapavo, C. De Simone, E. V. Di Brizzi, A. Di Cesare, V. Dini, M. Esposito, E. Errichetti, M. C. Fargnoli, C. S. Fiorella, A. Foti, Z. Fratton, F. M. Gaiani, P. Gisondi, R. Giuffrida, A. Giunta, C. Guarneri, A. Legori, F. Loconsole, P. Malagoli, A. Narcisi, M. Paolinelli, L. Potestio, F. Prignano, G. Rech, A. Rossi, N. Skroza, F. Trovato, M. Venturini, A. G. Richetta, G. Pellacani & A. Dattola (2024) Efficacy and Safety of bimekizumab in elderly patients: real-world multicenter retrospective study – IL PSO (Italian Landscape Psoriasis), Journal of Dermatological Treatment, 35:1, 2393376, DOI: 10.1080/09546634.2024.2393376

To link to this article: https://doi.org/10.1080/09546634.2024.2393376

Published online: 20 Aug 2024.

JOURNAL OF DERMATOLOGICAL TREATMENT
2024, VOL. 35, NO. 1, 2393376
https://doi.org/10.1080/09546634.2024.2393376

Taylor & Francis
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RESEARCH ARTICLE

Efficacy and Safety of bimekizumab in elderly patients: real-world multicenter retrospective study – IL PSO (Italian Landscape Psoriasis)

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ABSTRACT

Purpose of the article: The aim of this multicenter observational study is to report data from real world on the use of bimekizumab in patients aged ≥ 65 years with moderate-to-severe plaque psoriasis. Elderly patients are poorly represented in clinical trials on bimekizumab for plaque psoriasis, and real-world studies are important to guide clinical choices.

Materials and methods: A retrospective multicenter study was conducted in 33 dermatological outpatient clinics in Italy. Patients aged ≥ 65 years, with moderate-to-severe plaque psoriasis and treated with bimekizumab were enrolled. No exclusion criteria were applied. Bimekizumab was administered following the Italian Guidelines for the management of plaque psoriasis and according to the summary of product characteristics, in adult patients who were candidates for systemic treatments. Overall, 98 subjects were included, and received bimekizumab up to week 36. Clinical and demographic data were collected before the initiation of treatment with bimekizumab. At baseline and each dermatological examination (4, 16, and 36 weeks), clinical outcomes were measured by the following parameters: (1) PASI score; (2) site-specific (scalp, palmoplantar, genital, nail) Psoriasis Global Assessment (PGA). At each visit, the occurrence of any adverse events (AEs) was recorded, including serious AEs and AEs leading to bimekizumab discontinuation.

ARTICLE HISTORY
Received 12 July 2024
Accepted 8 August 2024

KEYWORDS
Bimekizumab; psoriasis; elderly; comorbidities

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Results: The mean PASI score was 16.6 ± 9.4 at baseline and significantly decreased to 4.3 ± 5.2 after 4 weeks ($p < 0.001$), and 1.1 ± 1.7 after 16 week ($p < 0.001$). This level of improvement was maintained after 36 weeks ($p < 0.001$). PASI ≤2 was recorded in 36 (36.7%) at week 4, 68% and 69.4% at week 16 and 36, respectively. By week 16, 86/98 (87.8%) patients reached PASI75, 71/98 (72.4%) obtained PASI90, and 52/98 (53.1%) PASI100. Binary logistic regression tests showed a significant association of PASI100 by week 4 with lower PASI at baseline. PASI 100 at 16 or 36 weeks was not associated with baseline PASI, obesity, age, gender, previously naïve state, and presence of psoriatic arthritis. Patients naïve to biologics at baseline had similar response to bimekizumab as non-naïve subjects.
Conclusions: Bimekizumab is a suitable option for elder patients as it is effective, tolerated and has a convenient schedule.

Introduction

Plaque psoriasis, affecting 1–3% of the world population, is associated with stigma, substantial psychosocial burden, and impaired quality of life (1). Additionally, physical comorbidities such as cardiovascular disease, diabetes and depression are often present (2). As a result, while mild-to-moderate psoriasis can be treated with topical therapy (corticosteroids and vitamin D3), systemic treatment is indicated for moderate-to-severe disease, especially if topical therapies have been ineffective (3,4). Therapy goals classically include obtaining prolonged remission of skin lesions and improvement of quality of life. Availability of biologic agents in the last years allowed to reach ambitious aims such as complete clearance of skin, and prevention or delay of psoriasis comorbidities, without any major tolerability issue (2).

Bimekizumab is a humanized monoclonal antibody inhibiting interleukin (IL)-17A and IL-17F. This IL is especially abundant in psoriatic lesions (5). It is approved for use in Europe for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy (6). Its efficacy and safety were demonstrated in phase 2 and 3 trials in patients with moderate-to-severe psoriasis, showing maintenance of response up to 3 years (7,8). Additionally, direct comparison trials showed the superiority of bimekizumab vs ustekinumab, secukinumab and adalimumab (9–11).

The aim of this multicenter observational study is to report data from real world on the use of bimekizumab in patients aged ≥ 65 years with moderate-to-severe plaque psoriasis. The elder population is rarely included in clinical trials as many subjects have factors considered exclusion criteria, such as polypharmacy and comorbidities. Nevertheless, elders are a relevant proportion of patients with plaque psoriasis in clinical practice and therefore data from observational studies are an important source of evidence to guide for therapeutic choices in this population with special tolerability and efficacy issues.

Patients and methods

A retrospective multicenter study was conducted between December 2022 and September 2023, in 33 dermatological outpatient clinics in Italy. Patients aged ≥ 65 years, with moderate-to-severe plaque psoriasis and treated with bimekizumab were enrolled. No exclusion criteria were applied. Bimekizumab was administered following the Italian Guidelines for the management of plaque psoriasis (3) and according to the summary of product characteristics, in adult patients who were candidates for systemic treatments (6). Two subcutaneous injections of 160 mg bimekizumab, for a total of 320 mg, were administered at week 0, 4, 8, 12, 16 and every 8 weeks thereafter. Institutional review board approval was exempted for this study as its procedure did not deviate from good routine clinical practice. All patients gave written informed consent for the retrospective retrieval of anonymized data. The study was conducted in accordance with the Helsinki Declaration of 1964 and its later amendments.

Data collection

Clinical and demographic data collected before the initiation of treatment with bimekizumab included gender, age, disease duration, body mass index (BMI), comorbidities including psoriatic arthritis, previous exposure to biological drugs, and the involvement of difficult-to-treat areas (scalp, palms/soles, genitalia, and nails). At baseline and each dermatological examination (4, 16, and 36 weeks), clinical outcomes were measured by the following parameters: (1) PASI – the improvements of 75%, 90% and 100% in PASI score compared with baseline (PASI 75, 90 and 100); (2) site-specific (scalp, palmoplantar, genital, nail) Psoriasis Global Assessment (PGA) of clear, almost clear, moderate, severe and very severe level.

For patients who did not attend the scheduled dermatological visits, data from the last available visit were used using the last-observation carried-forward analysis (a missing follow-up visit value is replaced by that subject's previously observed value).

At each visit, the occurrence of any adverse events (AEs) was recorded, including serious AEs and AEs leading to bimekizumab discontinuation.

Statistical analysis

Data were summarized by descriptive analysis. Means, median and standard deviations (SDs) were calculated for continuous variables,

Table 1. Clinical and demographic characteristics at baseline.

Characteristic	*N* = 98 *n* (%)/mean ± *SD*
Male	64 (65.3)
Age (years)	71.1 ± 5.5
Disease duration (years)	18.7 ± 17.8
BMI	28.0 ± 4.4
Obese	36 (36.7)
Diabetes	24 (24.5)
Hypertension	53 (54.1)
Hyperlipidemia	21 (21.4)
Thyroid disease	4 (4.1)
Oncologic disease	12 (12.2)
Cardiopathy	24 (24.5)
Other	11 (11.2)
Psoriatic arthritis	8 (8.2)
≥ 1 Difficult-to-treat areas	39 (39.8)
PASI at baseline	16.6 ± 9.4
Bio-naïve	46 (46.9)

while absolute values and frequency (%) were calculated for categorical variables. A *t*-test performed a comparison of mean values. The Wilcoxon-signed rank test was used to compare repeated measurements in each group, and the Mann–Whitney test compared mean data between groups. Binary logistic regression was used to assess the association of variables. All analyses were performed with IBM SPSS Statistics for Windows, Version 26.0. $p < 0.05$ was considered significant.

Results

Patients' characteristics

Demographic and clinical characteristics of patients at baseline are shown in Table 1.

Overall, the study population included 98 patients, of whom 64 (65.3%) were males. The mean age was 71.1 ± 5.5 years, the mean duration of psoriasis 18.7 ± 17.8 years, and the mean BMI 28 ± 4.4. The most frequent comorbidities were hypertension ($n = 53$, 54.1%), obesity ($n = 36$, 36.7%), diabetes ($n = 24$, 24.5%), and cardiopathy ($n = 24$, 24.5%). Difficult to treat areas of skin were involved by psoriasis in 39 (39.8%) subjects. At baseline, 46 (46.9%) patients were naïve to previous biologic agents, and 52 (53.0%) had received previous biologics. Among the 52 patients who had received a previous biologic therapy, 16 (30.8%) had received more than one agent. 19/39 (48.7%) patients with difficult to treat areas had previously been exposed to biologic agents. The following agents had been used: adalimumab ($n = 16$, 30.7%), ixekizumab (7, 13.4%), guselkumab ($n = 6$, 11.5%), secukinumab ($n = 6$, 11.5%), apremilast ($n = 5$, 9.6%), risankizumab ($n = 5$, 9.6%), brodalumab ($n = 3$, 5.8%), tildrakizumab ($n = 2$, 3.8%), etanercept ($n = 1$, 1.9%), and ustekinumab ($n = 1$, 1.9%). Previous biologic therapies had been discontinued because of lost efficacy ($n = 36$, 69.2%) or inefficacy ($n = 14$, 26.9%) in almost all cases.

All patients received bimekizumab up to week 36, were followed-up and were evaluable at that time point.

Table 2. Mean PASI score at each study time point.

Visit $N = 98$	Mean PASI ±*SD*	Mean PASI decrease ± DS	Wilcoxon matched-pair test
Baseline	16.6 ± 9.4		
4 weeks	4.3 ± 5.2	−12.3 ± 7.5	<0.001
16 weeks	1.1 ± 1.7	−15.5 ± 9.2	<0.001
36 weeks	1.1 ± 1.7	−15.5 ± 9.2	<0.001

Table 3. Site specific PGA scores at control visits. $N = 98$ at all time points. N (%).

	Baseline	4–week	16–week	36–week
Scalp PGA				
Clear	57 (58.2)	76 (77.6)	92 (93.9)	92 (93.9)
Almost clear	5 (5.1)	13 (13.3)	5 (5.1)	5 (5.1)
Mild	10 (10.2)	7 (7.1)	–	–
Moderate	18 (18.4)	2 (2.0)	1 (1.0)	1 (1.0)
Severe	7 (7.1)	–	–	–
Very severe	1 (1.0)	–	–	–
Palmoplantar PGA				
Clear	66 (67.3)	77 (78.6)	86 (87.8)	86 (88.8)
Almost clear	2 (2.0)	12 (12.2)	10 (10.2)	9 (9.2)
Mild	8 (8.2)	6 (6.1)	2 (2.0)	2 (2.0)
Moderate	10 (10.2)	3 (3.1)	–	–
Severe	9 (9.2)	–	–	–
Very severe	3 (3.1%)	–	–	–
Genital PGA				
Clear	81 (82.7)	88 (89.8)	97 (99.)	97 (99.0)
Almost clear	3 (3.1)	6 (6.1)	–	–
Mild	9 (9.2)	2 (2.0)	1 (1.0)	1 (1.0)
Moderate	4 (4.1)	2 (2.0)	–	–
Severe	–	–	–	–
Very severe	1 (1.0)	–	–	–
Nail PGA				
Clear	73 (74.5%)	74 (75.5%)	79 (80.6%)	80 (81.6%)
Almost clear	3 (3.1)	12 (12.2)	13 (13.3)	12 (12.2)
Mild	7 (7.1)	7 (7.1)	5 (5.1)	5 (5.1)
Moderate	9 (9.2)	4 (4.1)	1 (1.0)	1 (1.0)
Severe	5 (5.1)	1 (1.0)	–	–
Very severe	1 (1.0)	–	–	–

Efficacy

In the study population, the mean PASI score was 16.6 ± 9.4 at baseline. It significantly decreased to 4.3 ± 5.2 after 4 weeks ($p < 0.001$) of treatment with bimekizumab, and to 1.1 ± 1.7 after 16 week ($p < 0.001$). This level of improvement was maintained, although not further increased, after 36 weeks ($p < 0.001$) (Table 2).

PASI ≤2 was recorded in 36 (36.7%) patients at week 4, and 68 (69.4%) patients at week 16 and 36.

By week 16, 86/98 (87.8%) patients reached PASI75, 71/98 (72.4%) obtained PASI90, and 52/98 (53.1%) PASI100. The same mean improvement scores were maintained after 36 weeks (Figure 1). The probability of obtaining complete clearance of psoriasis (PASI 100) at week 4 was higher in patients with lower PASI score at baseline (binary logistic regression, odds ratio = 0.9; 95% CI: 0.9–1.0; $p = 0.029$). On the contrary, binary logistic regression tests showed no significant association of baseline PASI, obesity, age, gender, previously naïve state, and presence of psoriatic arthritis, with reaching PASI100 by week 16 or week 36 of treatment.

The efficacy of bimekizumab in difficult-to-treat areas was evaluated by site-specific PGA scores. Scalp psoriasis scored as moderate to very severe was present in 26 (26.5%) patients. 77.6% of these patients reached complete scalp psoriasis clearance at week 4 up to 93.9% at week 36.

Similarly, moderate to very severe palmoplantar lesions were recorded in 22 (22.4%) patients at baseline, with 78.6% reaching complete clearance at week 4 and up to 88.8% at week 36.

As regards genital psoriasis, 89.8% reached complete resolution at week 4 and up to 99.0% at week 36.

Finally, nails were involved by moderate to severe lesions in 15 (15.3%) patients at baseline, at week 4 75.5% of subjects reached complete resolution, with 81.6% obtaining resolution at week 36 (Table 3).

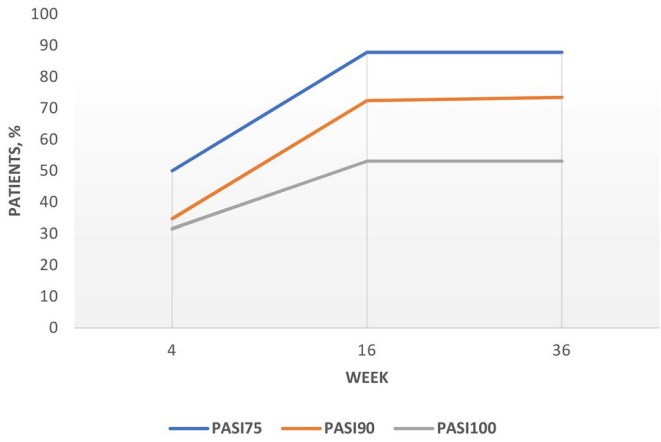

Figure 1. PASI75, PASI90 and PASI 100, at control visits during treatment with bimekizumab. $N = 98$.

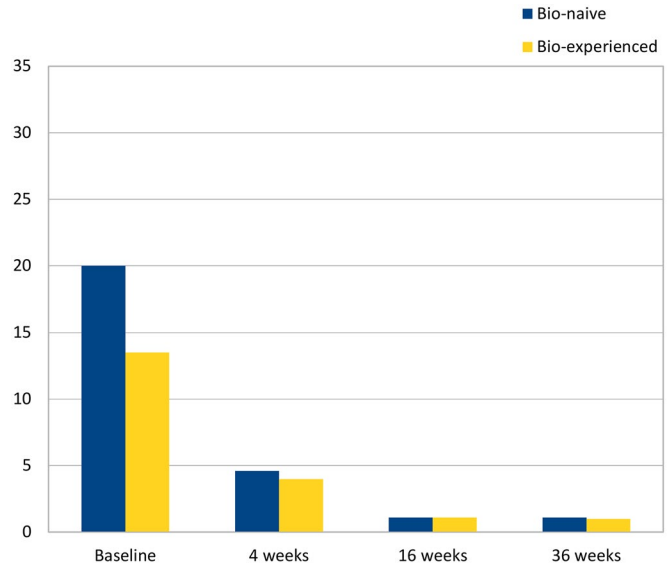

Figure 2. Mean PASI score in naïve and non-naïve patients to biologic treatment before bimekizumab at baseline and after 4, 16, and 36 weeks of treatment.

The patients naïve to biologics at baseline ($n=46$) had a mean PASI score of 20.0 ± 10.7, and those previously treated ($n=52$) of 13.5 ± 6.9 ($p=0.001$). The mean PASI score significantly decreased compared to baseline value both in naïve and non-naïve patients at each visit ($p<0.001$, all groups at all time points vs baseline). Nevertheless, it decreased at week 4 by -15.4 ± 8.3 in naïve subjects and by -9.5 ± 7.8 in non-naïve ones, and at weeks 16 and 36 by -18.8 ± 10.4 in naïve and -12.5 ± 6.8 in non-naïve patients. As a result, although naïve patients had a significantly higher mean PASI score at baseline, there was no significant difference between the two groups of patients at weeks 4, 16, and 36 (Figure 2).

The proportions of patients attaining PASI75, PASI90, and PASI100 were not significantly different in naïve and non-naïve patients at any time point, excepting PASI90 at week 16, that was obtained by 82.6% of naïve subjects and 63.5% of non-naïve ones ($\chi^2 = 0.035$).

As well, there was not a significant difference in the proportion of patients with PASI ≤ 2 at any study time.

Safety

In total, five patients (5.1%) reported adverse events. Two patients experienced mild eczema, and both were treated with a topical steroid. Three patients had oral candidiasis, treated with oral fluconazole. No interruption of bimekizumab therapy was necessary.

Discussion

Patients with moderate to severe psoriasis, aged ≥65 years, may be difficult to treat because tolerability is often reduced by comorbidities, concomitant treatments, as well as changes in metabolism (11,12). As the populations of clinical trials usually exclude subjects with comorbidities, older age and poorer health conditions, reducing the generalizability of results to the patients faced in clinical practice, we analyzed results obtained in the real world in elder patients treated with bimekizumab to provide information and guidance for therapeutic decisions in this type of patients.

In our experience, the 98 observed subjects tolerated bimekizumab, and could continue the therapy for at least 36 weeks without experiencing any major adverse events or treatment interruption, notwithstanding the high prevalence of hypertension, obesity, and diabetes (with concomitant treatments). Overall, the safety results were in line with previous findings from clinical trials (7–11). Most of them had a good response and more than 50% obtained complete clearance in 16 weeks, maintaining this result up to week 36.

We can detect some differences toward results obtained in younger and selected populations in the phase III clinical trials. PASI90 was obtained at week 16 in 86.2% patients in BE SURE (13), in 91% in BE READY (14), 81% in BE VIVID (9), and in 72.4% of our patients, suggesting that a slightly higher proportion of patients is resistant to bimekizumab in an advanced age. Similarly to younger patients, respondents to bimekizumab in our elder population maintained the improvement in the long term. These results seem to be in agreement with the results of a Japanese real-world study, by Hagino et al. (15), as the authors conclude that younger age may be predictive of a good response to bimekizumab.

In addition to the general response to bimekizumab, we evaluated whether a previous treatment with a biologic agent could impact the response to bimekizumab and realized that naïve patients had a higher decrease of the PASI score, and attained scores similar to those obtained by non-naïve subjects, although starting with higher baseline values. On the other end, the baseline mean score little impacted the response to bimekizumab in the overall population, suggesting that the steeper decrease of PASI in naïve subjects could be related to the absence of previous biologic treatment and not to the high baseline PASI score. We have no data from other real-world studies on the impact of previous treatment with a biologic agent; Ruiz-Villaverde et al. found a considerable response to bimekizumab in patients with plaque psoriasis, either naïve or non-naïve, but no comparison was possible in their population, as only 3 naïve subjects were included (16). Also, a 16-week multicenter study from Gargiulo et al. (17) did not show any impact of the previous exposure to biological therapies on the achievement of PASI 90 and PASI 100. Another study from Megna et al. (18) showed better clinical responses among bio-naïve patients after 4 weeks, but it did not report any significant difference between the two groups after 16 weeks of follow-up.

Regarding the involvement of difficult-to-treat areas, very limited data are available on the role of bimekizumab in treating this subset of patients. Our findings on genital psoriasis, however, are consistent with a recent multicenter experience, which found complete or almost complete skin clearance of genital psoriasis after 16 weeks of treatment with bimekizumab (19).

Limitations of this study include the observational retrospective design, the overall short follow-up, and the heterogeneity of comorbidities and general health condition. However, we believe that the present study adds to the current bulk of knowledge, by providing real-life information on the use of bimekizumab in an unselected population of elderly patients. These data can also become a reference for future studies.

In conclusion, although the proportion of responding subjects is slightly lower than obtained in clinical trials, bimekizumab was tolerated and had a good and prolonged efficacy in elder patients with moderate to severe psoriasis treated in a clinical practice setting. The recommended maintenance dose of 320 mg every 8 weeks makes bimekizumab convenient for non-compliant

patients, and this characteristic may be especially convenient for older subjects with polypharmacy.

Acknowledgements

Editorial assistance was provided by Aashni Shah, Valentina Attanasio, and Laura Brogelli (Polistudium, Milan, Italy).

Authors contributions

Study conception and design: Orsini D, Dattola A; collection and interpretation of data: Orsini D, Dattola A, Megna M, Balato A, Balestri R, Bernardini N, Bettacchi A, Bianchelli T, Buggiani G, Brunasso G, Burlando M, Caldarola G, Campanati A, Cameli N, Campione E, Carugno A, Chersi K, Conti A, Cuccia A, Dapavo P, D'Amico D, Dalbello G, Dini V, Esposito M, Errichetti E, Foti A, Fiorella C, Gisondi P, Guarneri C, Legori A, Loconsole F, Malagoli P, Narcisi A, Prignano F, Richetta AG, Trovato F, Venturini M, Pellacani G; statistical analysis: Orsini D, Dattola A; manuscript drafting: D. Orsini, A. Dattola; manuscript editing: Orsini D, Dattola A; approval to submit: Orsini D, Dattola A.

Ethical approval

Institutional review board approval was exempted for this study as its procedure did not deviate from good routine clinical practice. The study was conducted in accordance with the Helsinki Declaration of 1964 and its later amendments.

Informed consent

All patients gave written informed consent for the retrospective retrieval of anonymized data. All patients gave written informed consent for the publication of anonymized data.

Disclosure statement

D. Orsini has been a speaker and/or consultant for Abbvie, LeoPharma, UCB, Bristol-Meyer-Squibb and Boehringer- Ingelheim. A. Dattola has served as a speaker, consultant or advisory board member for Abbvie, Almirall, Amgen, Eli Lilly, Leo Pharma, Janssen, Novartis, Boehringer Ingelheim and UCB Pharma outside the submitted work. R. Balestri has received support for attending meetings and/or travel for AbbVie, Amgen, Leo Pharma, Lilly, Novartis and Sanofi. G. Rech has received support for attending meetings and/or travel for AbbVie, Amgen, Janssen, Lilly, and Novartis. G. Dal Bello has been consultant for Abbvie, Eli Lilly, Janssen, Sanofi, UCB and Novartis. F. Loconsole served on advisory boards and/or received honoraria for lectures from AbbVie, Janssen-Cilag, Novartis, Lilly, Sanofi. A. Costanzo has been a consultant and/or speaker for AbbVie, Almirall, Amgen, Janssen, Leo Pharma, Eli Lilly, Galderma, Boehringer, Novartis, Pfizer, Sandoz, and UCB. A. Narcisi has served on advisory boards, received honoraria for lectures and research grants from Almirall, AbbVie, BMS, Leo Pharma, Celgene, Eli Lilly, Janssen, Novartis, Sanofi-Genzyme, Amgen and Boehringer Ingelheim. P. Malagoli has been a speaker for AbbVie, Lilly, Novartis, Janssen-Cilag, Celgene, Leopharma, and Almirall. A. Balato has been a speaker and/or consultant for Abbvie, Almirall, Amgen, Boehringer- Ingelheim, Bristol-Meyer-Squibb, Janssen, Eli-Lilly, LeoPharma, Novartis, Sanofi, UCB. M. Megna acted as a speaker or consultant for: Abbvie, Amgen, Almirall, Eli Lilly, Novartis, Janssen, UCB, Leo Pharma. P. Gisondi acted as a speaker or consultant for Abbvie, Amgen, Almirall, Eli Lilly, Janssen, Leo-Pharma, UCB and Novartis Sanofi Plerre Fabre. 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, UCB. A. Cuccia has received grants for scientifics contributions from Abbvie, Alfasigma, Almirall, Amgen, Biogen, Boehringer Ingelheim, Cantabria Labs Difa Cooper, Janssen-Cilag, Lilly, Novartis, UCB. M. Burlando acted as a speaker or consultant for Abbvie, Eli Lilly, Janssen, Leo-Pharma, UCB, Novartis, Bristol-Meyer-Squibb and Boehringer- Ingelheim. E. Cozzani acted as a speaker or consultant for Abbvie, Almirall, Eli Lilly, Leo-Pharma, Novartis. A. Carugno has been a speaker and/or consultant for Almirall, Amgen, Abbvie, Boehringer-Ingelheim, Eli Lilly, Leo Pharma, Janssen-Cilag, Novartis, UCB Pharma. A. Conti has been a speaker and/or consultant for Abbvie, Almirall, Leo Pharma, UCB, Sandoz, Amgen, Biogen, Novartis, Janssen Cilag, Eli Lilly, Pfizer, Boehringer-Ingelheim. C. Guarneri has received consultation fees and/or grants for research projects, advisory panels and giving educational lectures from Wyeth-Pfizer, Abbott Immunology-Abbvie, Janssen-Cilag, Novartis, LEO-Pharma, LEO-Pharma Denmark, Ely-Lilly, Celgene, Merck-Serono, UCB Pharma, Sanofi-Aventis, Amgen and Almirall. G. Caldarola has received honoraria as speaker and consultant for Abbvie, Almirall, Biogen, Eli Lilly, LEO Pharma, Novartis, Janssen, Sanofi, Pfizer, and UCB Pharma outside the submitted work. C. De Simone has received honoraria as speaker or advisory board member or has participated in clinical trials for AbbVie, Almirall, Amgen, Leo Pharma, Eli Lilly, Janssen, Novartis, Pfizer, Sanofi Genzyme and UCB Pharma outside the submitted work. M. Esposito has served as speaker/consultant for Abbvie, Amgen, Almirall, Eli Lilly, Janssen, Leopharma, Novartis, Pfizer, Sanofi, UCB. A. Campanati has served as a speaker, consultant or advisory board member for Abbvie, Almirall, Amgen, Eli-Lilly, Leo Pharma, Janssen-Cilag, Novartis, Pfizer, Sanofi-Aventis, Boehringer Ingelheim and UCB Pharma. E. Errichetti has served as a Consultant/Speaker for Abbvie, Janssen-Cilag, Novartis, LEO-Pharma, UCB Pharma, Sanofi, Amgen and Almirall. N. Bernardini acted as a speaker or consultant for: Abbvie, Amgen, Almirall, Eli Lilly, Novartis, Janssen, UCB, Leo Pharma. FM. Gaiani acted as a speaker or consultant for Novartis, AbbVie, Eli Lilly, Celgene, LeoPharma, and Almirall. P. Dapavo has been a speaker for Novartis, AbbVie, Sanofi, UCB, Janssen, Lilly, and LeoPharma. M. Venturini has served as advisory board member and/or consultant and has received fees/speaker's honoraria and/or has participated in clinical trials for AbbVie, Almirall, Amgen, Bristol Myers Squibb, Boehringer-Ingelheim, Eli Lilly, Galderma, Janssen, Leo Pharma, Novartis, UCB Pharma.

Funding

This research was supported by Italian ministry of health Rc2024.

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Data availability statement

Additional data supporting the findings of this study are available from the Corresponding Author on reasonable request

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