ORIGINAL REPORT

Efficacy and Safety of Dupilumab in Immune Checkpoint Inhibitor Induced Bullous Pemphigoid: A Spanish Multicentric Case Series

Cecilia TEJERO-GARCÍA[1,2*], Francesc ALAMON REIG[3], Xavier BOSCH-AMATE[3], Cristina CARRERA[3,4,5], Priscila GIAVEDONI[3,4], Inmaculada GIL FAURE[6], Alicia JIMÉNEZ ANTÓN[7], Ander MAYOR IBARGUREN[8], Teresa USERO BÁRCENA[9], Marcial ÁLVAREZ-SALAFRANCA[10,11], Marta GAMISSANS CAÑADA[12], Joaquín LÓPEZ ROBLES[13], Sandra MARTÍNEZ-FERNÁNDEZ[14,15], Sonia SEGURA[16], Dolores SÁNCHEZ-AGUILAR ROJAS[1,2,17] and Ángeles FLÓREZ[1,2,17]

[1]Department of Dermatology, Complejo Hospitalario Universitario de Santiago de Compostela, Santiago de Compostela, Spain, [2]Translational Research Group in Dermatologic Diseases, Health Research Institute of Santiago de Compostela (IDIS), Santiago de Compostela, Spain, [3]Department of Dermatology, Hospital Clínic de Barcelona, University of Barcelona, Barcelona, Spain, [4]Institut d'Investigacions Biomèdiques August Pi i Sunyer (IDIBAPS), Barcelona, Spain, [5]Centro de Investigaciones Biomédicas en Red de Enfermedades Raras CIBERER, Instituto de Salud Carlos III, Madrid, Spain, [6]Department of Dermatology, Hospital Universitari Sant Joan de Reus, Tarragona, Spain, [7]Department of Dermatology, Hospital Universitario Puerta del Mar, Cádiz, Spain, [8]Department of Dermatology, Hospital Universitario La Paz, Madrid, Spain, [9]Department of Dermatology, Complejo Hospitalario Universitario de Ferrol, A Coruña, Spain, [10]Department of Dermatology, Hospital Universitario Miguel Servet, Zaragoza, Spain, [11]University of Zaragoza, Zaragoza, Spain, [12]Department of Dermatology, Hospital Universitario Bellvitge, Barcelona, Spain, [13]Department of Dermatology, Hospital General Universitario Morales Meseguer, Murcia, Spain, [14]Department of Dermatology, Complejo Hospitalario Universitario de Pontevedra, Pontevedra, Spain, [15]DIPO Research Group, Galicia Sur Health Research Institute (IIS Galicia Sur), SERGAS-UVIGO, Pontevedra, Spain, [16]Department of Dermatology, Hospital del Mar, Barcelona, Spain, and [17]University of Santiago de Compostela, Santiago de Compostela, Spain

Immune checkpoint inhibitors (ICIs) have significantly improved oncological outcomes. However, ICIs can elicit immune-mediated adverse effects that may require treatment discontinuation and potentially affect cancer prognosis. Bullous pemphigoid (BP) can be induced by ICIs in up to 1% of treated patients. Conventional treatments for BP (topical and systemic glucocorticoids as well as other classical immunosuppressants) associate substantial toxicities and may impair antitumour responses. Dupilumab, a monoclonal antibody that blocks IL-4/IL-13 signalling, represents a promising alternative, offering effective disease control with an improved safety profile. In this study, we assessed the efficacy and safety of dupilumab for the treatment of ICI-induced BP (ICI-BP) in a real-world multicentre case series of 19 patients, an underreported clinical setting. The median time to ICI-BP development from ICI initiation was 390 days (IQR 295). Overall, 18 patients (94.74%) achieved a clinical response, of whom 16 (84.21%) attained complete remission. Disease stabilization was observed in 1 patient. Among 17 patients receiving systemic corticosteroids prior to dupilumab, 14 (82.35%) discontinued them afterwards. Additionally, 11 patients (61.11 %; *n*=18) were able to continue or reintroduce ICI after dupilumab initiation. Dupilumab was well tolerated, with 18 patients (94.74%) experiencing no significant adverse events and only one case of suspected psoriasiform toxicity.

Key words: Dupilumab; Immune Checkpoint Inhibitors; Immunotherapy; Pemphigoid, Bullous; Safety; Treatment Outcome.

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SIGNIFICANCE

Immune checkpoint inhibitors are widely used to treat cancer and have significantly improved survival. However, they can sometimes cause immune-related side effects, including bullous pemphigoid, a skin disease that causes intense itching and blisters. Treating this condition is challenging because commonly used medications may cause major side effects and interfere with the body's ability to fight cancer by weakening the immune system. In our multicentre Spanish study of 19 patients, dupilumab, a targeted biologic therapy which blocks specific inflammatory signals, proved to be both effective and safe in most cases, suggesting a promising treatment option for this complication.

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Corr: Cecilia Tejero-García, Department of Dermatology, Complejo Hospitalario Universitario de Santiago de Compostela, Travesía da Choupana, s/n, 15706 Santiago de Compostela, A Coruña, Spain. Email: cecilia.tejero.garcia@sergas.es

Immune checkpoint inhibitors (ICIs) represent a key milestone in modern oncology. These agents block tumour-expressed molecules that impair the antitumour immune response, thereby reactivating and enhancing T-cell activity. They have been approved across diverse malignancies, including melanoma, lung and genitourinary cancers, among others (1). Their indications have progressively expanded into neoadjuvant and adjuvant regimens alongside their established role in advanced disease (2).

Restoration of the immune response elicited by ICIs can lead to loss of self-tolerance, resulting in immune-related adverse events (irAEs) in 40% of treated patients (3). The skin is among the most

commonly affected organs in irAEs, with a wide range of manifestations and severities (4). ICI-induced BP (ICI-BP) is estimated to occur in 0.2% to 1% of patients treated with ICIs (5, 6). The clinical presentation and diagnostic approach resemble those of classical BP. Treatment of BP-ICI depends on disease severity and the patient's baseline condition. First-line management relies on high-potency topical corticosteroids and oral corticosteroids (0.5–1 mg/kg/day) (7, 8). Steroid-sparing agents are mentioned but are not clearly positioned within treatment algorithms specifically addressing ICI-BP (7, 8). Immunosuppressants used for non-ICI-BP (methotrexate, azathioprine, mycophenolate (9)) carry an unfavourable risk-benefit profile in oncology patients due to systemic toxicity, immunosuppression and potential to interfere with immunotherapy efficacy. ICI discontinuation (either temporary or permanent) is necessary in 58–75% of BP-ICI cases, and if treatment is reinitiated, 50 % of patients may experience disease recurrence (6).

Dupilumab is a humanized monoclonal antibody that binds to the interleukin-4 receptor alpha subunit (IL-4Rα), thereby inhibiting signalling of both IL-4 and IL-13. This agent is approved for atopic dermatitis, prurigo nodularis and chronic spontaneous urticaria, in addition to respiratory conditions. Most recently, the United States Food and Drug Administration (FDA) granted approval for BP in adults in a non-oncologic setting (10). To date, information on its use in BP-ICI is scarce and limited to isolated case reports or small case series. Although these data are promising, high-quality evidence remains limited, highlighting the need for further studies.

For these reasons, the present study aims to evaluate the real-world efficacy and safety of dupilumab in the treatment of BP-ICI using local data. Its use is expected to facilitate the continuation of oncologic therapy, potentially improving patient prognosis, while reducing the cutaneous burden of disease and enhancing quality of life.

MATERIALS AND METHODS

We conducted a multicentre, ambispective case series. Over a 5-month period (from July 16, 2025, to December 15, 2025), patients were recruited from 11 hospital centres in Spain. Inclusion criteria comprised patients aged 18 years or older with acute BP-ICI in the oncologic setting which had received or were receiving dupilumab.

The dermatologist responsible for each patient completed a standardized data collection form distributed to all participating centres. The form included demographic, clinical, laboratory and outcome variables. Demographic features recorded were age at BP-ICI diagnosis, sex, primary cancer and tumour stage. The specific ICI received and the time interval from immunotherapy initiation to BP-ICI diagnosis were also documented. Clinical data included a description of cutaneous lesions. Histopathological diagnosis was based on skin biopsy findings along with direct immunofluorescence (DIF). Enzyme-linked immunosorbent assay (ELISA) was performed against BP antigen 180 (BP180) and BP antigen 230 (BP230). Serum IgE levels were also recorded.

For efficacy and safety analyses, the dupilumab dosing regimen and any concomitant treatments administered before and during dupilumab therapy were documented. Management of the underlying ICI was also assessed, specifically whether it was permanently discontinued or temporarily withheld due to BP or maintained despite BP. BP-ICI response to dupilumab was categorized as complete response (CR), defined as complete epithelialization of all lesions with no new lesions during the follow-up period; partial response (PR), defined as objective clinical improvement without achieving CR; and no response (NR), which included stable disease – defined as the absence of progression or clinical improvement – and disease progression – defined as an increase in the number, size, or extension of cutaneous lesions. Total duration of dupilumab treatment, recurrence of BP and the time interval to recurrence were also recorded. Adverse events associated with dupilumab were defined as any new medical episode or exacerbation of a preexisting medical condition in a patient treated with dupilumab, for which a causal relationship with the drug was suspected or confirmed.

Clinical data were abstracted from electronic medical records by the treating dermatologists. As assays and reporting formats for immunologic parameters varied across centres, these markers were analysed dichotomously.

Statistical analysis

The statistical analysis of quantitative variables was performed using median and interquartile range (IQR), while qualitative variables were analysed through absolute and relative frequencies. All analyses were performed using Jamovi software (Version 2.6), based on the R statistical environment. Missing data were handled by complete-case analysis. Descriptive and outcome analyses were conducted using all available data for each variable, and the effective sample size is reported accordingly.

RESULTS

A total of 19 patients with BP-ICI were included. **Table I** shows the cohort demographics and ICI therapies received. The median age of BP-ICI diagnosis was 77

Table I. Demographic characteristics and ICI therapies in a 19-patient BP-ICI case series

	Absolute frequency	Relative frequency	Median, IQR (range)
Age of onset of BP-ICI			77, 9 (53-95)
Sex			
Male	18	94.74	
Female	1	5.26	
Primary cancer			
Melanoma	8	42.11	
Lung adenocarcinoma	4	21.05	
Cholangiocarcinoma	1	5.26	
Clear cell renal cell carcinoma	1	5.26	
Colon adenocarcinoma	1	5.26	
Cutaneous squamous cell carcinoma	1	5.26	
Endometrial adenocarcinoma	1	5.26	
Hepatocellular carcinoma	1	5.26	
Laryngeal squamous cell carcinoma	1	5.26	
ICI received			
Pembrolizumab	11	57.89	
Nivolumab	6	31.58	
Cemiplimab	2	10.53	
Days from ICI initiation to BP onset			390, 295 (52-2,089)

BP: bullous pemphigoid; BP-ICI: bullous pemphigoid induced by immune checkpoint inhibitors; ICI: immune checkpoint inhibitor; IQR: interquartile range.

years (IQR 9) and 18 patients were males (94.74%). The most prevalent primary malignancy was melanoma (8 cases; 42.11%), followed by lung adenocarcinoma (4 cases; 21.05%). None of the patients had a previous history of BP. All cases developed the disease after receiving anti-programmed cell death protein 1 (anti-PD1) ICI-subtype, being pembrolizumab the agent reported in 11 cases (57.89%). One patient developed BP immediately after completing ICI therapy. The median number of days from ICI initiation to BP onset was 390 days (IQR 295).

Clinical features and laboratory findings are presented in **Table II**. Classical manifestations of BP were observed in 17 patients (89.47%) and oral mucous involvement in 3 patients (15.79%). Sixteen biopsies (84.21%) showed subepidermal blister with eosinophilia and positive DIF with linear deposition of IgG and/or C3 along the basement membrane, consistent with BP. Eight patients had elevated total IgE levels (72.73 %; *n*=11).

Efficacy and safety outcomes are presented in **Table III**. ICI treatment was discontinued in 7 patients

Table II. Clinical features of BP-ICI and laboratory findings in patients with bullous pemphigoid induced by immune checkpoint inhibitors (BP-ICI)

	Absolute frequency	Relative frequency
Clinical presentation of BP-ICI		
Erythematous-edematous plaques with tense blisters and erosions on trunk and extremities	17	88.47
Oral mucosal involvement	3	15.79
Erythematous scaly papules on chest and arms	1	5.26
Maculopapular eruption on trunk and lower limbs with fixed associated urticarial lesions	1	5.26
ELISA		
anti-BP180 (*n*=18)		
+	13	72.22
–	5	27.78
anti-BP230 (n=12)		
+	3	25
–	9	75
IFD (n=18)		
+	16	88.89
–	2	11.11
Biopsy (HE)		
Eosinophilic subepidermal bullous dermatitis	16	84.21
Vacuolar interface dermatitis with necrotic keratinocytes, focal parakeratosis, and a superficial dermal infiltrate mainly composed of lymphohistiocytes	1	5.26
Acanthosis, spongiosis and perivascular lymphocytic infiltrate	1	5.26
Superficial dermatitis with eosinophilia	1	5.26
IgE (*n*=11)		
Elevated	8	72.73
Normal	3	27.27

BP180: bullous pemphigoid antigen 180; BP230: bullous pemphigoid antigen 230; DIF: direct immunofluorescence; ELISA: Enzyme-Linked immunosorbent assay; HE: haematoxylin and eosin staining.

Table III. Immune checkpoint inhibitor (ICI) management after bullous pemphigoid induced by immune checkpoint inhibitors (BP-ICI) development and dupilumab treatment outcomes

	Absolute frequency	Relative frequency	Median, IQR (range)
ICI management due to BP-ICI (*n*=18)			
ICI suspension	7	38.89	
ICI temporary discontinuation	6	33.33	
ICI maintenance	5	27.78	
ICI continuation or reintroduction rate	11	61.11	
Previous treatment regimens for ICI-BP			
Topical corticosteroids	19	100	
Systemic corticosteroids	17	89.47	
Dapsone	5	26.32	
Doxycycline	4	21.05	
Nicotinamide	3	15.79	
Topical calcineurin inhibitor	1	5.26	
Dupilumab dosing regimes			
Loading dose of 600 mg followed by 300 mg/2 weeks	15	78.95	
300 mg/2 weeks	4	21.05	
Dose de-escalation to 300 mg/6 weeks	1	5.26	
Response to dupilumab			
Complete response	16	84.21	
Partial response	2	10.53	
No response: stable disease	1	5.26	
No response: progressive disease	0		
Response rate	18	94.74	
Non-response rate	1	5.26	
Concomitant treatments with dupilumab for BP-ICI			
Yes	15	78.95	
Topical corticosteroids	13	68.42	
Systemic corticosteroids	4	21.05	
Topical calcineurin inhibitor	1	5.26	
No	4	21.05	
Systemic corticosteroid discontinuation after dupilumab initiation (*n*=17)	14	82.35	
No systemic concomitant treatment (*n*=19)	15	78.95	
Total duration of dupilumab treatment (days)			240, 298 (28–789)
ICI-BP recurrence/ no recurrence (*n*=18)			
Recurrence	2	11.11	
No recurrence	16	88.89	
Time to recurrence of BP from dupilumab initiation (days) (*n*=2)			139
Dupilumab-related adverse events			
Yes	1	5.26	
No	18	94.74	

ICI management was analysed in 18 patients, excluding the case that developed BP-ICI immediately after completing adjuvant oncologic treatment with an ICI.
IQR: interquartile range.

(38.89%), temporarily withheld in 6 (33.33%), and maintained in 5 (27.78%). Previously to dupilumab, almost all patients received topical (19 patients; 100%) and systemic corticosteroids (17 patients; 89.47%) without reaching BP's control.

CR with dupilumab was achieved in 16 patients (84.21%) after a median time of follow up of 240 days (IQR 298) (**Fig. 1**). Two patients showed PR (10.53%) and one, NR with stabilization of BP (5.26%). Fourteen patients (82.35%; *n*=17) were able to suspend systemic corticosteroids after dupilumab initiation. Fifteen patients (78.95%) did not require concomitant systemic treatment. Four patients achieved sustained control of BP-ICI with dupilumab monotherapy (21.05%). After initiation of dupilumab, among patients achieving clinical response, 16 patients (88.89%; *n*=18) maintained remission of BP-ICI, while 2 experienced recurrence (11.11%; *n*=18). Regarding safety, dupilumab was well-tolerated, with no adverse events reported in 18 patients (94.7%) after a median follow up of 240 days (IQR 298). One patient (5.26%) developed a psoriasiform reaction without requiring dupilumab suspension.

All data collected from the cohort is displayed as Tables SI and SII.

DISCUSSION

The demographics of our BP-ICI cohort were consistent with previous reports, with a median age at onset of 77 years and a strong male predominance (94.74%) (11). Correspondingly, the most frequent cancer types were melanoma (8 cases, 42.11%) and non-small cell lung cancer (NSCLC) (4 cases, 21.05%) (6, 12). Notably, BP-ICI occurred exclusively in patients treated with anti-PD-1 agents, in line with published data (12). None of the patients had a history of BP prior to ICI initiation, distinguishing our cohort from the monocentric 17-patient series by Nykaza et al. (13).

The classical BP presentation was the most common (17 patients; 89.47%) and three patients (15.79%) also exhibited oral mucosal involvement, concordant with Tsiogka et al. findings (14). Two patients presented with intense pruritus and non-bullous lesions, consistent with a recognized prebullous phase of BP-ICI (15). ELISA was positive for anti-BP180 in 72.22% and for anti-BP230 in 25 % of the tested patients, in line with prior reports (6). Lesions usually emerge at a median of 26 weeks after immunotherapy initiation (range 2-209 weeks) (6), whereas latency was longer in our cohort (median 390 days; range 52-2089 days).

Most of the published data on the efficacy of dupilumab in BP-ICI derive from single case reports (16–23) and small case series (13, 24–27), all of which support our findings. In the Nykaza et al. series, dupilumab achieved a CR in 75% of cases (13). A retrospective study of dupilumab in ICI-induced pruritic dermatoses, which included 21 cases of BP, reported that 18 patients (85.71%) showed CR or PR after a median treatment time of 8 months; however, segregated response and recurrence data were not

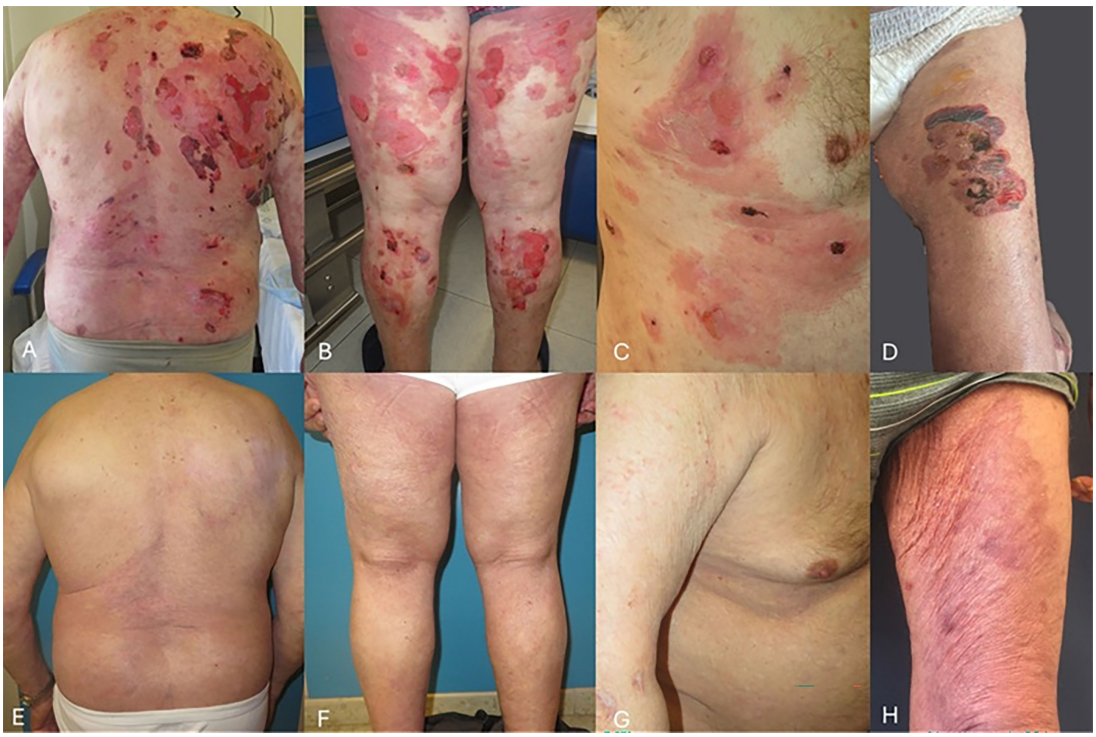

Fig. 1. Clinical image of patients #18 and #1 before (A–D) and after complete response with dupilumab treatment (E–H).

reported (27). Although these results confirm the high efficacy of dupilumab, the response rates were lower than those observed in our series (94.74% response ratio, with 84.21% CR). Notably, the only patient in our cohort with NR but BP-ICI stabilization had received dupilumab for just 43 days. In classical BP, CR rates of up to 83.5% at week 16 have been published (28). For BP-ICI, the median time to first dupilumab response has been reported as 19.5 days, with best response at 109.5 days (13). Therefore, the limited treatment duration of our case may have constrained the assessment of efficacy, although it allowed avoidance of previously administered systemic corticosteroids.

Persistence of response with dupilumab was observed in 16 patients (88.89 %; *n*=18), with a median treatment duration of 240 days (IQR 298). Data on this topic are scarce and heterogeneous, as follow-up periods vary across reports. In our cohort, we observed two recurrences. One occurred after 202 days of treatment, coinciding with a doubling of the ICI dose. In contrast, Grüninger et al. reported safe escalation to dual immunotherapy without BP recurrence (20). The second recurrence consisted of a localized relapse after 76 days of dupilumab despite an initial rapid CR, suggesting suboptimal treatment duration or early resistance.

In general, the atopic dermatitis dosing regimen of dupilumab has been used for BP-ICI (13, 16, 23, 24, 27). Consistent with our series (4 patients, 21.05%), efficacy without a loading dose has also been previously documented (20–23). One patient remains in CR while tapering dupilumab (300 mg every 6 weeks) after more than 1 year of treatment. Evidence in this setting is limited and published cases after discontinuation have shown both sustained resolution and relapse (26).

Following dupilumab initiation, 15 patients (78.95%) required no additional systemic treatment, notably higher than reported in the series by Nykaza et al., in which 61% of patients received dupilumab monotherapy (13). This is a key point, since systemic glucocorticoids are associated with significant risks in oncology patients (29). In NSCLC, glucocorticoids administered after ICI initiation have been associated with worse progression-free survival; nevertheless, further studies are needed to confirm this effect (30).

BP-ICI prognostic significance remains controversial (31, 32). Furthermore, the severity of irAEs may require ICI discontinuation. In this context, a longer duration of ICI treatment prior to discontinuation due to irAEs has been associated with improved outcomes in patients with advanced NSCLC (33). In our cohort, only 7 patients (38.89%) required ICI suspension; previously reported data showed a mildly lower suspension rate (29.4 %; *n*=17) (13). In patients not treated with dupilumab, BP-ICI has been associated with ICI discontinuation rates of up to 75% (6). Further studies are warranted, although dupilumab may facilitate longer ICI maintenance.

Regarding safety, dupilumab was well-tolerated in 18 patients (94.74%) with no reports of cancer relapse attributable or likely related to dupilumab, consistent with previous data (13, 27). One patient developed severe psoriatic onychopathy 2 months after initiating dupilumab therapy. Similar lesions had been noted on the patient's right toe prior to BP-ICI development, suggesting possible psoriatic background. Psoriasiform reactions have been described secondary to both ICI and dupilumab (34, 35). Therefore, the etiology of this toxicity remains unclear. High tolerability of dupilumab in our cohort aligns with findings from smaller case series, highlighting its potential as a safe and effective option in this fragile population (13, 16–27).

Our study is limited by the sample size of 19 patients, variability in follow-up durations at the time of data collection, and the ambispective design, all of which constrain the strength and generalizability of our findings.

In conclusion, our findings highlight the efficacy and safety of dupilumab for the treatment of BP-ICI. Effective control of this irAE may significantly improve patients' quality of life and oncologic outcomes by facilitating continued immunotherapy. This BP-ICI cohort represents one of the largest reported to date, providing valuable real-world evidence to guide clinicians in managing this challenging condition.

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Data availability statement: The datasets generated and/or analysed during the current study are available from the corresponding author on reasonable request.

IRB approval status: The study was registered and received ethics approval from the Research Ethics Committee on Medicinal Products of Galicia (CEIm-G) (Registration Code: 2025/448). Patient anonymity and data confidentiality were guaranteed throughout the study.

Conflict of interest: CTG has received financial support for training activities from Abbvie, Janssen, Lilly, Novartis, Roche Farma, Sanofi and UCB Pharma. XBA has received honouraria or support for training activities, has acted as a speaker, consultant or has participated in clinical trials from Abbvie, Galderma, Incyte, Novartis, Regeneron, Sanofi and Viñas. CC declares educational fees from International School of Derma ISD, Roche, Janssen and La Roche Posay-L'Oreal, and support to attend congress/conferences by ISDIN, Pierre Fabre, Sanofi and Bristol Meyers Squibb, none of them related with the present manuscript. AMI has received honouraria or support for training activities, has acted as a speaker, consultant or has participated in clinical trials from Abbvie, Almirall, Amgen, BMS, Celgene, Incyte, Janssen, Johnson&Johnson, Leo-Pharma, Lilly, MSD, Novartis, Pfizer, Roche Farma, Sanofi, Sun Pharma, Takeda and UCB Pharma. TUB has received support for training activities, has acted as a speaker or has participated in clinical

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