Title

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Journal

Dermatology and Therapy, 14(5)

ISSN

2193-8210

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Publication Date

2024-05-01

DOI

10.1007/s13555-024-01162-8

Peer reviewed

Dermatol Ther (Heidelb) (2024) 14:1349–1357
https://doi.org/10.1007/s13555-024-01162-8

BRIEF REPORT

Brodalumab: 5-Year US Pharmacovigilance Report

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Received: January 31, 2024 / Accepted: April 8, 2024 / Published online: May 9, 2024

ABSTRACT

***Introduction*:** Brodalumab is a human interleukin-17 receptor A antagonist indicated for the treatment of moderate-to-severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies. Although the US prescribing information for brodalumab includes a boxed warning regarding suicidal ideation and behavior, no causal association has been demonstrated. Here, we summarize 5 years of pharmacovigilance data, from August 15, 2017, through August 14, 2022, reported to Ortho Dermatologics by US patients and healthcare providers.

***Methods*:** Prevalence of the most common adverse events (AEs) listed in the brodalumab package insert (incidence ≥ 1%) and AEs of special interest are described. Brodalumab exposure was estimated as the time from the first to last prescription-dispensing authorization dates. Data were collected from 4744 patients in the USA, with an estimated exposure of 5815 patient-years.

***Results*:** Over 5 years, 11 cases of adjudicated major adverse cardiovascular events were reported (0.23 events/100 patients), a rate lower than that experienced by patients in the international Psoriasis Longitudinal Assessment and Registry. There were 106 serious infections. No serious fungal infections were reported. There were 40 confirmed and 2 suspected COVID-19

Prior Presentation: Data included in this publication have been previously presented in part at the Fall Clinical Dermatology Conference; October 19–22, 2023; Las Vegas, NV; Maui Derm Hawaii; January 22–26, 2024; Maui, HI; and Winter Clinical Dermatology Conference – Hawaii®; January 12–17, 2024; Maui, HI.

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cases, with no new COVID-19-related deaths. Of 49 reported malignancies among 42 patients, 3 were deemed possibly related to brodalumab. No completed suicides and no new suicidal attempts were reported.
Conclusion: Five-year pharmacovigilance data are consistent with the established safety profile reported in long-term clinical trials and previous pharmacovigilance reports, with no new safety signals.

PLAIN LANGUAGE SUMMARY

Brodalumab is an injectable treatment approved for moderate-to-severe plaque psoriasis in adults who lacked response to previous treatments. In the USA, brodalumab is only available under a Risk Evaluation and Mitigation Strategy for increased suicidality risks; however, findings from 5 years of real-world safety data have demonstrated a lack of association. In this report, we discuss safety findings reported by US patients and healthcare providers for 4744 patients treated with brodalumab over 5 years. Joint pain (known as arthralgia) was the most common safety finding, with 122 cases reported over 5 years. Other safety findings of interest across 5 years included 106 serious infections (defined as prolonged infections or infections requiring treatment), 54 cases of depression, 49 cases of cancer (in 42 patients), 40 confirmed cases of COVID-19, and 11 cases of major cardiovascular events (such as stroke or heart attack). No completed suicides occurred throughout 5 years, and no new suicidal attempts were reported in year 5. In indirect comparisons with safety data from patients with psoriasis receiving or eligible to receive similar treatments, brodalumab was not associated with an increased risk of serious infection, cancer, major cardiovascular events, or inflammatory bowel disease. Taken together, these data are consistent with safety findings from long-term clinical trials and previous safety reports of brodalumab.

Keywords: Adverse events; Drug reaction; Psoriasis; Real-world; Safety

Key Summary Points

Why carry out the study?

Brodalumab, a human interleukin-17 receptor A antagonist indicated for treatment of moderate-to-severe plaque psoriasis in adults, carries a boxed warning in the US prescribing information regarding suicidal ideation and behavior.

Because patients with psoriasis often require long-term treatment, ongoing monitoring of adverse events (AEs) is necessary to establish the safety profile of brodalumab in a real-world setting.

This report summarizes 5 years (August 15, 2017–August 14, 2022) of brodalumab pharmacovigilance data reported to Ortho Dermatologics by US patients and healthcare providers with a focus on the most common AEs listed in the brodalumab package insert and AEs of special interest, including suicide and depression.

What was learned from the study?

The most commonly reported AE was arthralgia (122 total events); no new suicide attempts were reported in year 5, and no completed suicides were reported throughout the 5 years.

This 5-year pharmacovigilance report supports the consistent safety profile of brodalumab established in pivotal trials and previous pharmacovigilance reports, with no new safety signals.

INTRODUCTION

Brodalumab, a human anti–interleukin-17 receptor A monoclonal antibody, is indicated for the treatment of moderate-to-severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy and are unresponsive

to other systemic therapies [1]. The safety profile of brodalumab has been described in one phase 2 study, multiple phase 3 studies, and US pharmacovigilance reports for years 1 through 4 [2–9]. Brodalumab carries a boxed warning in the US prescribing information regarding suicidal ideation and behavior and is only available under a Risk Evaluation and Mitigation Strategy (REMS) in the US despite no established causal relationship between brodalumab and suicidality during pivotal trials or subsequent pharmacovigilance reports [1, 10]. Additionally, in brodalumab clinical trials, there were no specific exclusion criteria regarding history of psychiatric disorders, history of suicidality, known suicidality risk factors, or current or past substance abuse diagnoses [10].

There is a need to evaluate long-term safety concerns in real-world practice to fully characterize the safety profile of brodalumab. We recently described the 4-year US pharmacovigilance data of brodalumab, highlighting its consistency with the established safety profile reported in long-term clinical trials and previous pharmacovigilance reports [9]. In the current report, we detail 5-year pharmacovigilance data in the US as an update to the 4-year report [9].

METHODS

This analysis summarizes pharmacovigilance data reported by US patients and healthcare providers (HCPs) to Ortho Dermatologics (a division of Bausch Health US, LLC), which markets brodalumab in the US. Data are from August 15, 2017, through August 14, 2022. The prevalence of the most common adverse events (AEs) listed in the brodalumab package insert (i.e., AEs with an incidence ≥ 1%) [1] and other AEs of special interest are summarized with descriptive statistics.

Overall drug exposure was estimated as the time between the initial and last prescription-dispensing authorization dates. Detailed medical histories, previous psoriatic therapies, time intervals between previous therapy and brodalumab initiation, and AE dates were either missing or not included in pharmacovigilance reports [5]. Thus, crude AE reporting rates per 100 patients are reported here.

Ethics approval and informed consent were not required, as the postmarketing data summarized in this report were noninterventional and were not collected as part of a clinical study. The collected data were nonidentifiable.

RESULTS

Exposure and Unique Cases

Within the 5-year period, data were collected from 4744 US patients who were administered brodalumab, with an estimated exposure of 5815 patient-years. Of the 4744 US patients, 2292 (48%) had ≥ 1 AE reported; 24% were reported by HCPs and 76% were reported by patients.

Common AEs

In the brodalumab package insert, common AEs listed include arthralgia, headache, fatigue, diarrhea, oropharyngeal pain, nausea, myalgia, injection-site reactions, influenza, neutropenia, and *Tinea* infections [1]. During the 5-year pharmacovigilance period, arthralgia was the most commonly reported AE, as previously reported in the 4-year report [9]. There were seven new cases of arthralgia (122 total events) since the 4-year report, reducing the crude AE reporting rate from 2.86 events/100 patients in year 4 to 2.57 events/100 patients in year 5. Since the 4-year report, there were two new cases of myalgia (0.70 events/100 patients) and three new cases of injection-site reactions (0.80 events/100 patients). There was one new case each of headache (0.97 events/100 patients), fatigue (0.95 events/100 patients), and oropharyngeal pain (0.46 events/100 patients) in year 5. There were no new cases of diarrhea (0.70 events/100 patients), nausea (0.61 events/100 patients), influenza (0.48 events/100 patients), or neutropenia (0.02 events/100 patients). In the US, no *Tinea* infections were reported throughout the 5 years.

Other AEs of Special Interest

Other AEs that have been deemed of special interest by the reporter or company include adjudicated major adverse cardiovascular events (MACE), serious infections, fungal infections, inflammatory bowel disease (IBD), malignancy, depression, and completed suicide (Fig. 1).

Adjudicated MACE

Adjudicated MACE was medically confirmed by the reporting HCP. The crude AE reporting rate of adjudicated MACE for the 5-year period (0.23 events/100 patients) was less than that of the Psoriasis Longitudinal Assessment and Registry (PSOLAR; 1.55 events/100 patients), an international registry that enrolled patients with psoriasis who were receiving or eligible to receive systemic or biologic therapy [11]. Throughout the 5 years, 11 cases of adjudicated MACE were reported including stroke ($n=1$), ischemic stroke ($n=1$), acute coronary syndrome ($n=1$), left carotid stenosis ($n=1$), myocardial infarction ($n=5$), unstable angina ($n=1$), and coronary artery bypass procedure ($n=1$). For most of these cases (10/11; 91%), patients had a known history of cardiovascular-associated risk factors, medications, or diagnoses/complications. Five patients (45%) were reported to have continued brodalumab after the event.

Infections

Serious infections (i.e., prolonged infections or infections requiring intervention) were defined as any Medical Dictionary for Regulatory

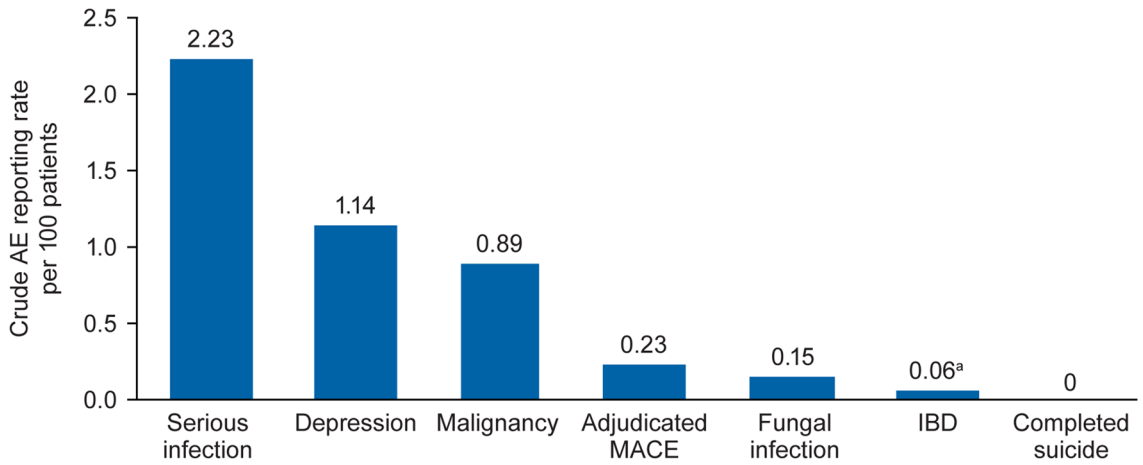

Fig. 1 Crude reporting rates of AEs of special interest, as deemed by the reporter or company, per 100 patients. Crude AE reporting rate per 100 patients is the number of AEs of special interest divided by 4744 brodalumab patients multiplied by 100 patients. Completed suicide events ($n=0$) are reported. Clinical events of special interest were defined using MedDRA v25.0 terms. Serious infection (i.e., prolonged infection or infection requiring intervention) included any MedDRA PT identified under the SOC name *Infections and infestations*, for which the SOC was indicated as "primary" and event seriousness as "serious." Depression included MedDRA PTs from *Depression* (excluding *Suicide* and *Self-injury*) SMQ (narrow). Malignancy included MedDRA PTs from *Malignancies* SMQ and *Malignant lymphomas* SMQ. Adjudicated MACE included MedDRA PTs from *Ischemic CNS vascular conditions* SMQ, *Ischemic heart disease* SMQ (*Myocardial infarction*), and *Ischemic heart disease* SMQ (*Other*), and where "medically confirmed" was blank. Fungal infection included MedDRA HLTs from *Fungal infections* NEC. Inflammatory bowel disease included MedDRA PTs *Inflammatory bowel disease, Irritable bowel syndrome, Crohn's disease*, and *Colitis ulcerative*. *AE* adverse event, *CNS* central nervous system, *HLT* High-Level Term, *IBD* inflammatory bowel disease, *MACE* major adverse cardiovascular event, *MedDRA v25.0* Medical Dictionary for Regulatory Activities, version 25.0; *NEC* not elsewhere classified, *PT* Preferred Term, *SMQ* standardized MedDRA query, *SOC* System Organ Class. [a]Excluding one nonvalid case of Crohn's disease

Activities Preferred Term identified under the System Organ Class (SOC) name "infections and infestations," for which the SOC was indicated as "primary" and event seriousness as "serious." Overall, 106 serious infections were reported, four (4%) of which were determined to be related to brodalumab. The rate of serious infections (2.23 events/100 patients) decreased compared with the 4-year report (2.54 events/100 patients) [9], and no serious fungal infections were reported throughout the 5 years. There were four new cases of candida infections; however, all four patients continued brodalumab. There were no new cases of other fungal infections, hepatitis, or tuberculosis (including latent infection or reactivation) compared with the 4-year report [9]. There was one case of tuberculosis in year 4; the reporter provided no information regarding previous or concomitant psoriasis therapies, travel history, or past medical history [9]. One previous nonviral case of "inflammation of the liver" (labeled as hepatitis) was reported before year 5 for a patient with a "gallbladder disorder."

Since the beginning of the pandemic, there were 40 cases of confirmed COVID-19 and 2 cases of suspected COVID-19. Among these cases, 33 (79%) patients had underlying comorbid conditions, and the remaining 9 (21%) provided no information regarding comorbidities. Compared with the 4-year report, there were no new deaths due to COVID-19 [9].

Inflammatory Bowel Disease

One patient who started brodalumab in May 2022 with a history of Barrett's esophagus, hypertension, mastocytic enterocolitis, and acid reflux reported irritable bowels and sun sensitivity in July 2022. This patient continued brodalumab.

One new case of Crohn's disease was reported; however, this case was considered nonvalid owing to the lack of patient identifiers (e.g., medical history, concomitant medications, therapy start/stop date) despite multiple follow-up attempts with the reporter. The nonvalid case was not included in the 5-year report.

Malignancy

The crude AE reporting rate for malignancy in year 5 (0.89 events/100 patients; 49 malignancies reported in 42 cases) was similar to that in year 4 (0.80 events/100 patients; 37 malignancies reported in 32 cases) [9] and less than that in PSOLAR (1.78 events/100 patients [excluding nonmelanoma skin cancer]) [11]. Types of reported malignancies in new cases included endometrial and uterine cancers; dermatologic malignancies, such as nonmelanoma skin cancer (both basal cell carcinoma and squamous cell carcinoma) and cutaneous T-cell lymphoma (mycosis fungoides); and an unclassified neoplasm (carcinoma removed from left hip). Of the ten new cases, four patients continued and six patients discontinued brodalumab. Three (6%) of the reported malignancies throughout the 5 years of data were deemed possibly related to brodalumab (keratoacanthoma-type squamous cell carcinoma, basal cell carcinoma, and unspecified neoplasm [carcinoma removed from left hip]).

Depression and Previous Case of Suicide Attempt

Throughout 5 years of pharmacovigilance reporting, there were 54 documented cases of depression, reducing the 4-year event rate of 1.29 events/100 patients to 1.14 events/100 patients. There were four (7%) cases of depression deemed as related to brodalumab, all of which occurred before the 4-year pharmacovigilance report [4, 9]; for the two new cases of depression in year 5, no causality assessments were provided by the reporter. No new suicide attempts were reported in year 5, one suicide attempt was previously reported [4], and no completed suicides were reported throughout the 5 years.

DISCUSSION

This US pharmacovigilance report summarizes 5 years of the most common AEs from

the brodalumab package insert and additional AEs of special interest reported from August 15, 2017, through August 14, 2022. Consistent with clinical trials and previous pharmacovigilance reports, brodalumab exhibited a tolerable safety profile with no new safety signals reported. There were no new reports of diarrhea, nausea, influenza, or neutropenia; in the US, no *Tinea* infections have been reported. Among 11 cases of adjudicated MACE, most patients (91%) had a history of cardiovascular-associated risk factors, medications, or diagnoses/complications. Across 5 years, there were 40 cases of confirmed COVID-19 and 2 cases of suspected COVID-19; there were no COVID-19-related deaths during year 5. Most patients with COVID-19 (79%) had underlying comorbid conditions. Among 54 documented cases of depression, 4 (7%) were reported to be related to brodalumab (as described in the 3-year pharmacovigilance report) [4, 9]. No new cases of suicide attempts were reported during year 5, and no completed suicides were reported throughout the 5 years.

To contextualize crude rates of AEs of special interest reported here, we conducted indirect comparisons with those of other recent observational studies. PSOLAR was an intercontinental registry including 12,095 patients with psoriasis receiving or eligible to receive biologic or systemic therapy (median follow-up, 2.5 years) [11]. Crude rates reported in this 5-year report vs those calculated from PSOLAR were lower for adjudicated MACE (0.23 vs 1.55 events/100 patients), serious infections (2.23 vs 3.95 events/100 patients), and malignancy (0.89 vs 1.78 events/100 patients [excluding nonmelanoma skin cancer in PSOLAR]). Furthermore, we compared the crude rate of IBD observed here (0.06 events/100 patients) with that calculated from a 20-year Danish study, which included a cohort of 235,038 patients with psoriasis receiving topical, systemic, or biologic therapy [12]. The crude rate of definite Crohn's disease and/or ulcerative colitis was 0.32 events/100 patients among those receiving any therapy (mean follow-up, ~6.8 years) and 0.14 events/100 patients among those receiving biologic therapy (mean follow-up, ~3.7 years). It should be noted that the prescribing information for brodalumab lists Crohn's disease as a contraindication [1], and the crude rate of IBD reported here may therefore be lower than that observed in other broader populations with psoriasis; however, it is unlikely that this contributed to the lower rate observed in the present comparison because the Danish study excluded patients with a history of confirmed or suspected IBD. Thus, brodalumab is not associated with a heightened risk of adjudicated MACE, serious infection, malignancy, or IBD compared with other systemic or biologic therapies. However, results from both indirect comparisons have limited interpretability due to various factors, including a lack of objective controls and potentially different diagnostic criteria for AEs of special interest.

Several limitations related to the nature of pharmacovigilance reporting apply here. For instance, only AEs reported to Ortho Dermatologics were documented, and the lack of controlled comparison groups hinders the interpretation of findings. Furthermore, because exact brodalumab administration dates are not available, patient-exposure estimates are based on prescription-dispensing authorization dates. Additionally, there is a lack of contextual information (which is typical in data reported via pharmacovigilance channels), thus restricting our interpretation of the association between brodalumab and reported AEs. Lastly, because brodalumab is only available through a restricted REMS program in the US [1], patients with a history of significant depression would probably be prescreened and not given treatment. Thus, it could be argued that the patient population in this report may not be representative of a real-world distribution of depression. However, a real-world analysis of patients with psoriasis initiating biologic therapy at or after enrollment in the CorEvitas (formerly Corrona) Psoriasis Patient Registry showed that prevalence rates of history of depression were similar among those initiating brodalumab (23%), IL-12/23 or IL-23 inhibitors (26%), or non-brodalumab IL-17A inhibitors (27%) [13]. These findings suggest that despite restrictions imposed by the REMS program, rates of depression observed in this pharmacovigilance report may indeed reflect those of a real-world population. Regardless of potential selection biases, if a treatment were to cause a particular AE, it is generally reasonable

to expect its occurrence within both screened and age-matched nonscreened populations.

CONCLUSION

When selecting an optimal therapy for psoriasis, HCPs and patients must balance patient-specific factors, efficacy, and risk of AEs [14, 15]. This 5-year US pharmacovigilance report supports the consistent safety profile of brodalumab established in pivotal trials and previous pharmacovigilance reports. Notably, no new cases of suicide attempts were reported in year 5, and no completed suicides were reported throughout the 5 years in the US. Overall, brodalumab was well tolerated, with no new safety signals emerging after 5 years of pharmacovigilance monitoring.

Medical Writing and Editorial Assistance.. Writing and editorial assistance were provided under the direction of the authors by Ella A. Kasanga, PhD, PMP®, and Jenna Lewis, MA, ELS, of MedThink SciCom, and funded by Ortho Dermatologics. Ortho Dermatologics is a division of Bausch Health US, LLC.

Author's disclosures.. Mark G. Lebwohl is an employee of Mount Sinai; receives research funds from AbbVie, Arcutis, Avotres, Boehringer Ingelheim, Cara Therapeutics, Clexio, Dermavant Sciences, Eli Lilly, Incyte, Inozyme, Janssen, Pfizer, Sanofi-Regeneron, and UCB; and is a consultant for Almirall, AltruBio, Apogee, Arcutis, AstraZeneca, Atomwise, Avotres, Boehringer Ingelheim, Bristol-Myers Squibb, Castle Biosciences, Celltrion, CorEvitas, Dermavant Sciences, Dermsquared, Evommune, Facilitation of International Dermatology Education, Forte Biosciences, Galderma, Genentech, Incyte, LEO Pharma, Meiji Seika Pharma, Mindera, Pfizer, Sanofi-Regeneron, Seanergy Dermatology, Strata, Takeda, Trevi Therapeutics, and Verrica.

Author Contributions. All authors meet International Committee of Medical Journal Editors criteria for authorship for this article. Mark G. Lebwohl contributed to the conception and design of the study. Nicole N. Rawnsley and Earl L. Goehring Jr contributed to the acquisition of data. Mark G. Lebwohl, John Y. Koo, April W. Armstrong, Nicole N. Rawnsley, Earl L. Goehring Jr, and Abby A. Jacobson contributed to the analysis and interpretation of data. John Y. Koo, Nicole N. Rawnsley, and Abby A. Jacobson contributed to drafting the manuscript. Mark G. Lebwohl, John Y. Koo, April W. Armstrong, Bruce E. Strober, George M. Martin, Nicole N. Rawnsley, Earl L. Goehring Jr, and Abby A. Jacobson contributed to critically revising the manuscript for important intellectual content. All authors have given final approval of the manuscript for publication and agree to be accountable for all aspects of the work.

Funding. Funding for this study and the journal's Rapid Service Fee was provided by Ortho Dermatologics (a division of Bausch Health US, LLC).

Data Availability. The data sets generated or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Conflict of Interest. Mark G. Lebwohl is an employee of Mount Sinai; has received research funds from AbbVie, Amgen, Arcutis, Avotres, Boehringer Ingelheim, Cara Therapeutics, Dermavant Sciences, Eli Lilly, Incyte, Inozyme, Janssen Research & Development, Ortho Dermatologics, Pfizer, Sanofi-Regeneron, and UCB; and has been a consultant for Almirall, AltruBio, AnaptysBio, Arcutis, AstraZeneca, Avotres Therapeutics, Brickell Biotech, Boehringer Ingelheim, Bristol-Myers Squibb, Castle Biosciences, Celltrion, CorEvitas, Dermavant Sciences, EPI, Evommune, Facilitation of International Dermatology Education, Forte Biosciences, Foundation for Research and Education in Dermatology, Galderma, Genentech, Incyte, LEO Pharma, Meiji Seika Pharma, Mindera, Pfizer, Seanergy, Strata, Trevi, and Verrica. John Y. Koo has been a consultant or speaker for AbbVie, Amgen,

Eli Lilly, EPI, Janssen, LEO Pharma, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sanofi, and Sun Pharmaceutical. April W. Armstrong has served as a research investigator for and/or scientific advisor to AbbVie, Almirall, Arcutis, ASLAN, Beiersdorf, Boehringer Ingelheim, Bristol-Myers Squibb, Dermavant Sciences, Dermira, EPI, Incyte, Janssen, LEO Pharma, Lilly, Mindera, Nimbus, Novartis, Ortho Dermatologics, Pfizer, Regeneron, Sanofi, Sun Pharmaceutical, and UCB. Bruce E. Strober has been an investigator, scientific director, consultant, or member of a speakers bureau or advisory board for AbbVie, Amgen, AstraZeneca, Boehringer Ingelheim, Celgene, CorEvitas Psoriasis Patient Registry, Cutanea-Maruho, Dermira, Eli Lilly, GlaxoSmithKline, Janssen, LEO Pharma, Medac Pharma, Novartis, Pfizer, Sun Pharmaceutical, and UCB; has received grant support for a fellowship program from AbbVie and Janssen; and has received investigational/grant support payments for the University of Connecticut. George M. Martin has served as a consultant, speaker, or scientific advisory board member for AbbVie, Almirall, Alumis, Bristol-Myers Squibb, Celgene, Dermavant, DUSA/Sun Pharmaceutical, Eli Lilly, Evelo, Galderma, Horizon, Incyte, Janssen, LEO Pharma, Nobelpharma, Organogenesis, Ortho Dermatologics, Pfizer, Trevi Therapeutics, and UCB. Nicole N. Rawnsley, Earl L. Goehring Jr, and Abby A. Jacobson are employees of Bausch Health Companies Inc.

Ethical Approval. Ethics approval and informed consent were not required, as the post-marketing data summarized in this report were noninterventional and were not collected as part of a clinical study.

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