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ORIGINAL RESEARCH

Five-year Maintenance of Clinical Response and Consistent Safety Profile for Guselkumab in Asian patients with Psoriasis from VOYAGE 1 and VOYAGE 2

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ABSTRACT

Introduction: Guselkumab is a human monoclonal antibody against IL-23 used in the treatment of moderate-to-severe psoriasis. This post-hoc analysis evaluated the efficacy and safety of guselkumab in the Asian subpopulation of VOYAGE 1 and VOYAGE 2 through 5 years.

Methods: The proportions of guselkumab-treated Asian patients (VOYAGE 1 and 2) achieving Psoriasis Area and Severity Index (PASI) 90 and PASI 100, Investigator's Global Assessment (IGA) scores of 0/1 and 0, and Dermatology Life Quality Index (DLQI) scores of 0/1 (week 100 through week 252) were assessed. Non-responders were patients who met the treatment failure rules. Efficacy endpoints were analyzed using the as-observed methodology (no missing data imputation) for both studies and using non-responder imputation (for patients with any missing data) in VOYAGE 1. Safety outcomes were based on pooled data through week 252.

Results: Response rates through week 252 for 199 Asian patients in the guselkumab group in VOYAGE 1 and VOYAGE 2, respectively, were 76.8% and 80.6% (PASI 90), 26.8% and 38.7%

Prior Publication: These data have not been published previously. However, the global data that include the Asian patient subgroup have been published: Baluvelt A et al. JAAD 2017;76(3):405–17; Reich K et al. JAAD 2016;76(3):418–31; Reick K et al. JAAD 2020;82(4):936–45; Reich K et al. Br J Dermatol 2021;185(6):1146–59.

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(PASI 100), 64.3% and 87.1% (IGA 0/1), and 26.8% and 45.2% (IGA 0). DLQI (0/1) at week 252 was achieved by 52.7% of patients in VOYAGE 1 and 61.3% in VOYAGE 2, while DLQI (0) at week 252 was achieved by 32.7% of patients in VOYAGE 1 and 40.3% in VOYAGE 2. The safety profile was similar to the global population and remained consistent through 5 years. Asian patients were followed for a total of 814 patient-years (PY). Over 85% of the guselkumab-treated patients continued treatment through week 264. The rate of serious adverse events (AEs) at week 252 was 3.07/100 PY. Rates of AEs of interest were low: serious infections, 0.74/100 PY; nonmelanoma skin cancer (NMSC), no patients; malignancies other than NMSC, 0.12/100 PY; and no major adverse cardiovascular events (MACE).

Conclusion: These analyses confirm a continuous response over 5 years, indicating that guselkumab shows therapeutic longevity in Asian patients requiring long-term treatment for moderate-to-severe psoriasis.

Trial Registration: ClinicalTrials.gov identifiers: VOYAGE 1 [NCT02207231] and VOYAGE 2 [NCT02207244].

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PLAIN LANGUAGE SUMMARY

Psoriasis—a long-term condition that causes a skin rash with scaly, itchy patches (plaques)—is becoming more prevalent in Asia. To control symptoms of moderate-to-severe psoriasis and achieve a strong improvement in the patient's quality of life, continuous treatment is usually needed. Guselkumab is a medicine that targets specific parts of the immune system to treat moderate-to-severe psoriasis. It is important to understand the long-term benefits of guselkumab in Asian patient populations. Our study analyzed the data from two randomized clinical trials (called VOYAGE 1 and VOYAGE 2) that studied people with moderate-to-severe plaque psoriasis. We examined results for the 199 people from Asia, including Korea and Taiwan, who took part in these studies. Overall, 162 of the 184 (86.6%) people from Asia treated with guselkumab incorporated into these studies continued the treatment for 5 years. Patients treated with guselkumab showed effective clinical responses (improvements measured by clinicians), including high skin clearance, meaning a large reduction in skin surface area affected by psoriasis. On guselkumab, patients also reported improvements in their skin-related health-related quality of life. These improvements and the efficacy of guselkumab were maintained over 5 years of follow-up. The safety results for guselkumab in the Asian subpopulation were similar to those for the global population, showing low rates of serious adverse effects, as expected from this type of medicine. Overall, our study found a favorable benefit–risk profile with continuous guselkumab treatment for 5 years in Asian people with moderate-to-severe psoriasis. This highlights that guselkumab treatment allows long-lasting control of this disease.

Keywords: Asian; Biologics; Guselkumab; Moderate-to-severe; Psoriasis

Key Summary Points

The prevalence of psoriasis is increasing in Asia, and continuous treatment is needed to maintain an optimal response.

While there are short-term efficacy and safety data for guselkumab in Asian patients with psoriasis, long-term data in this population are lacking.

This post-hoc analysis utilized Asian population data from two phase III, randomized, double-blind, placebo- and adalimumab comparator-controlled studies of guselkumab.

Continuous treatment with guselkumab over 5 years showed a favorable benefit–risk profile in Asian patients with moderate-to-severe psoriasis.

These findings indicate an agent with a potential for therapeutic longevity in the Asian population.

INTRODUCTION

Psoriasis is a serious global problem, with reported country prevalences ranging from 0 to 11.43% [1] and East Asian countries reporting an increasing prevalence of this chronic condition [2, 3]. Studies of psoriasis prevalence in China, Japan, South Korea and Taiwan estimate rates ranging from 0.12 to 2.14% [1–6]. As a chronic disease, moderate-to-severe psoriasis usually requires continuous treatment to maintain a response. Thus, long-term efficacy and safety data are crucial to inform the treatment-decision-making process. Another consideration is that with an increasingly aging population, effective treatments with a low risk of side effects are paramount [7]. Furthermore, studies in Asian and Western populations have reported differences in the expression of genes and human leukocyte antigen (HLA) that play a role in the pathophysiology and maybe even the treatment response of psoriasis [8], highlighting the importance of assessing the safety and efficacy of therapeutic agents specifically in the Asian population [9–13].

The current therapeutic options for this systemic inflammatory disease include topicals, phototherapy, conventional systemic treatments (e.g., methotrexate, cyclosporine), as well as biologics and small molecules [14]. In particular, biologics have transformed treatment for moderate-to-severe psoriasis, [7, 15], as there are drugs available that target IL-23 (guselkumab, risankizumab, tildrakizumab) and IL-17 (secukinumab) and anti-tumor necrosis factor (TNF) therapies (adalimumab) [14, 15].

Guselkumab is a fully human immunoglobulin G1 lambda monoclonal antibody. It binds with high affinity and specificity to the IL-23 p19 subunit and inhibits IL-23-mediated intracellular and downstream signaling [16]. As a key regulator of multiple cell types, IL-23 plays a crucial role in the pathogenesis of psoriasis [17, 18]. It is essential for the survival and expansion of T-helper 17 cells, which are part of the cascade contributing to skin inflammation in psoriasis [17, 18].

In two 48-week (1-year) phase III global clinical trials (VOYAGE 1 [NCT02207231] and VOYAGE 2 [NCT02207244]) that included both Asian and non-Asian populations, guselkumab demonstrated superior efficacy to placebo and adalimumab, a commonly used TNF-α inhibitor, and was well tolerated in patients with moderate-to-severe plaque psoriasis [19, 20]. Long-term guselkumab data have demonstrated the maintenance of clinical response and a consistent safety profile to week 156 (3 years) in patients from VOYAGE 1 and VOYAGE 2 [21], to week 204 (4 years) in patients from VOYAGE 1 [22], and to week 252 (5 years) in patients from both studies [23].

While a post-hoc analysis comparing the Asian and non-Asian subpopulations of VOYAGE 1 and VOYAGE 2 found comparable responses for overall efficacy and safety in the short term (up to week 24) for these two subpopulations [24], data that are specific to long-term outcomes in the Asian subpopulation are needed. Here, we report the efficacy results and pooled safety data from a post-hoc analysis of

the Asian subpopulation across VOYAGE 1 and VOYAGE 2 through 5 years of treatment with guselkumab.

METHODS

Patients

VOYAGE 1 and VOYAGE 2 were multinational trials including centers in the USA, Canada, Poland, Czech Republic, Germany, Spain, Russia, Australia, South Korea and Taiwan (VOYAGE 1 only). For the purpose of this post-hoc analysis, patients recruited at centers located in Taiwan and South Korea were defined as Asian. Patients of Asian descent that participated at centers located in non-Asian countries were considered non-Asian due to the potential influence of differences in culture, health policies and types of treatments between Asian and non-Asian countries. Patient inclusion and exclusion criteria were identical for both trials. Eligible patients were $\geq$ 18 years of age, had a diagnosis of moderate-to-severe plaque psoriasis (defined as a score of $\geq$ 3 in the Investigator's Global Assessment [IGA], $\geq$ 12 in the Psoriasis Area and Severity Index [PASI], and $\geq$ 10% body surface area [BSA] involvement) for at least 6 months and were candidates for phototherapy or systemic psoriasis treatments (detailed inclusion and exclusion criteria are described elsewhere) [19].

Study Design

Details of the study designs have been published elsewhere [19–23]. Both VOYAGE 1 and VOYAGE 2 were phase III, multicenter, randomized, double-blind, placebo- and adalimumab comparator-controlled studies of guselkumab in moderate-to-severe psoriasis. While both studies evaluated the efficacy of guselkumab through week 252, and safety through week 264, VOYAGE 1 included a crossover to adalimumab at week 52 and VOYAGE 2 included a randomized withdrawal and retreatment period at weeks 28–76 [23]. Both studies were conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practices. The study protocols were approved by institutional review boards or independent ethics committees, including Sterling Institutional Review Board. All participants provided written informed consent.

Efficacy and Safety Parameters

In VOYAGE 1 and VOYAGE 2, disease severity was evaluated based on standard psoriasis measures, including the PASI score and IGA, with evaluations performed at regular visits through week 252. Skin-related health-related quality of life (HRQoL) was self-reported by patients using dermatology-specific assessments, including the Dermatology Life Quality Index (DLQI). Safety was monitored by adverse event (AE) reporting and laboratory investigations.

In this Asian subpopulation (patients recruited at centers located in Taiwan and South Korea), analyses were conducted on a 'combined guselkumab group' using pooled data from VOYAGE 1 and VOYAGE 2, including placebo patients who crossed over to guselkumab and patients randomized to adalimumab at week 0 who crossed over to guselkumab at or after week 52. Prior biologic experience at baseline was also considered for this combined guselkumab group.

Statistical Analysis

This post-hoc analysis presents efficacy data from week 100 through week 252 from VOYAGE 1 and VOYAGE 2. Although all patients from the two studies received guselkumab from week 76, cross-study comparisons at week 100 and beyond were considered to be the most informative, as they recognized the possibility that some patients withdrawn from treatment in VOYAGE 2 may have restarted or initiated guselkumab as late as week 72. At week 100, all patients had received a continuous regimen of guselkumab for at least 28 weeks, allowing for

meaningful evaluation of efficacy outcomes across both studies.

The proportions of patients achieving nearly complete clearance (PASI 90 and an IGA score of 0/1), complete clearance (PASI 100 and an IGA score of 0), and no impact of psoriasis on HRQoL (DLQI of 0/1) are summarized. Efficacy data are presented for the guselkumab group (including patients randomly assigned to receive placebo at baseline who then crossed over to guselkumab at week 16) and the adalimumab-to-guselkumab group (patients randomly assigned to receive adalimumab who then crossed over to receive guselkumab) for each study.

In the prespecified analysis, patients who met treatment failure rules (TFR)—defined as discontinuation due to lack of efficacy, worsening of psoriasis, or the use of a protocol-prohibited psoriasis treatment—were considered non-responders, with no other missing data imputation for efficacy endpoints. To assess the robustness of the prespecified analyses, efficacy endpoints were analyzed with the as-observed methodology (no missing data imputation) for both studies and non-responder imputation (NRI) (patients with any missing data were counted as non-responders) in VOYAGE 1 (wherein patients received continuous treatment through week 252). Because of the randomized withdrawal design, NRI analyses were not performed for VOYAGE 2.

Safety data are summarized for patients receiving at least one dose of guselkumab. Data were pooled across the two studies and calculated as incidence per 100 patient-years (PY) of follow-up through week 264. These analyses focused mainly on the safety of guselkumab in patients receiving continuous treatment for up to week 252 (i.e., the guselkumab group, including placebo crossovers). Reported AEs included serious AEs, malignancies (non-melanoma skin cancer [NMSC] and malignancies other than NMSCs), major adverse cardiovascular events (MACEs), and serious infections. For completeness, cumulative safety data are presented for the combined guselkumab group (including the guselkumab and adalimumab-to-guselkumab groups).

RESULTS

Baseline Demographics

A total of 199 Asian patients were included in this post-hoc analysis: 101 patients in VOYAGE 1 (placebo, $n = 22$; guselkumab, $n = 43$; adalimumab, $n = 36$) and 98 in VOYAGE 2 (placebo, $n = 23$; guselkumab, $n = 51$; adalimumab, $n = 24$). Baseline demographics and disease characteristics were generally comparable across the two studies (Table 1). VOYAGE 2 had a higher proportion of patients with an IGA score of 'severe', and VOYAGE 1 had a higher proportion of patients with self-reported psoriatic arthritis.

Patient Disposition

Around 80% of all patients (Asian and non-Asian) in VOYAGE 1 and VOYAGE 2 continued through week 252. Overall, 19.6% of patients (152 of 774) in VOYAGE 1 and 23.4% (222 of 949) in VOYAGE 2 discontinued the study agent. Rates of discontinuation due to lack of efficacy were low for the guselkumab groups (1.4% in VOYAGE 1 and 1.0% in VOYAGE 2). An AE of worsening of psoriasis led to discontinuation in 0.4% of patients in VOYAGE 2 [23].

Over 85% of all Asian patients in VOYAGE 1 and VOYAGE 2 continued through week 252.

Overall, 9.6% of Asian patients (9 of 94) in VOYAGE 1 and 13.3% of Asian patients (12 of 90) in VOYAGE 2 discontinued the study agent from baseline (for those originally randomized to guselkumab) and from the time of crossover to guselkumab (for those originally ramdomized to placebo or adalimumab) through week 252. Rates of discontinuation due to lack of efficacy were low for the guselkumab groups (1.6% in VOYAGE 1, and no patients discontinued due to lack of efficacy in VOYAGE 2). There were no patient discontinuations due to an AE of worsening of psoriasis in either VOYAGE 1 or VOYAGE 2 for the Asian subpopulation.

Table 1 Summary of patient demographics, characteristics, and disease characteristics in Asian patients in VOYAGE 1 and VOYAGE 2

	VOYAGE 1 (*n* = 101)			VOYAGE 2 (*n* = 98)		
	Placebo	**Guselkumab**	**Adalimumab**	**Placebo**	**Guselkumab**	**Adalimumab**
Patients randomized, *n*	22	43	36	23	51	24
Age (years), mean ± SD	42.1 (13.33)	40.7 (11.85)	38.3 (11.84)	43.1 (10.28)	41.6 (12.59)	37.9 (7.10)
Men, *n* (%)	14 (63.6%)	33 (76.7%)	30 (83.3%)	17 (73.9%)	40 (78.4%)	20 (83.3%)
Weight (kg)						
Mean ± SD	73.7 (14.94)	77.3 (17.88)	82.5 (16.31)	75.0 (14.02)	75.7 (17.19)	77.6 (14.51)
> 90 kg, *n* (%)	3 (13.6%)	8 (18.6%)	9 (25.0%)	3 (13.0%)	7 (13.7%)	4 (16.7%)
> 70 to ≤ 90 kg, *n* (%)	8 (36.4%)	18 (41.9%)	21 (58.3%)	11 (47.8%)	26 (51.0%)	13 (54.2%)
≤ 70 kg, *n* (%)	11 (50.0%)	17 (39.5%)	6 (16.7%)	9 (39.1%)	18 (35.3%)	7 (29.2%)
Height (cm), mean ± SD	167.9 (7.09)	168.7 (9.09)	168.9 (9.09)	169.1 (8.77)	169.7 (8.02)	171.2 (8.08)
BMI (kg/m^2), mean ± SD	26.1 (4.72)	27.1 (5.68)	28.8 (4.85)	26.1 (3.71)	26.1 (4.75)	26.4 (3.81)
Duration of psoriasis (years), mean ± SD	12.6 (6.71)	15.2 (10.47)	13.2 (7.24)	12.6 (6.07)	15.3 (9.38)	10.4 (6.69)
Psoriatic arthritis, *n* (%)	5 (22.7%)	9 (20.9%)	7 (19.4%)	2 (8.7%)	3 (5.9%)	3 (12.5%)
BSA (%), mean ± SD	32.7 (16.75)	35.6 (18.22)	34.8 (20.84)	32.6 (18.64)	30.5 (14.33)	33.5 (22.13)
PASI (0–72), mean ± SD	24.94 (9.945)	26.16 (9.130)	27.72 (12.164)	24.24 (8.647)	23.45 (8.804)	25.40 (13.397)
IGA score						
Moderate, *n* (%)	16 (72.7%)	33 (76.7%)	24 (66.7%)	15 (65.2%)	35 (68.6%)	15 (62.5%)
Severe, *n* (%)	6 (27.3%)	10 (23.3%)	12 (33.3%)	8 (34.8%)	16 (31.4%)	9 (37.5%)
DLQI (0–30), mean ± SD	18.1 (6.34)	19.0 (7.18)	18.5 (6.82)	19.4 (7.25)	17.3 (6.17)	18.7 (7.11)
Prior psoriasis treatment, *n* (%)						
Phototherapy (PUVA or UV-B)	14 (63.6%)	38 (88.4%)	30 (83.3%)	22 (95.7%)	44 (86.3%)	19 (79.2%)

Table 1 continued

	VOYAGE 1 (n = 101)			VOYAGE 2 (n = 98)		
	Placebo	Guselkumab	Adalimumab	Placebo	Guselkumab	Adalimumab
Non-biologic systemics*	16 (72.7%)	41 (95.3%)	32 (88.9%)	19 (82.6%)	46 (90.2%)	22 (91.7%)
Biologics†	5 (22.7%)	9 (20.9%)	10 (27.8%)	7 (30.4%)	17 (33.3%)	6 (25.0%)
Non-biologic systemics or biologics	17 (77.3%)	41 (95.3%)	32 (88.9%)	20 (87.0%)	46 (90.2%)	23 (95.8%)

*Non-biologics include PUVA, methotrexate, cyclosporin, acitretin, apremilast, or tofacitinib. †Biologics include etanercept, infliximab, alefacept, efalizumab, ustekinumab, briakinumab, secukinumab, ixekizumab, or brodalumab

BMI body mass index, *BSA* body surface area, *DLQI* Dermatology Life Quality Index, *IGA* Investigator's Global Assessment, *PASI* Psoriasis Area and Severity Index, *PUVA* psoralen plus ultraviolet A, *SD* standard deviation, *UV-B* ultraviolet B

Clinical Response

Clinical responses in Asian patients treated with guselkumab were maintained over time in both VOYAGE 1 and VOYAGE 2, demonstrating consistent results from week 100 through week 252. In the prespecified TFR analysis of VOYAGE 1, the proportion of patients achieving a PASI 90 response in the guselkumab group at weeks 100 and 252 was, respectively, 76.2% and 76.8%, and the proportion achieving a PASI 100 response at weeks 100 and 252 was, respectively, 34.9% and 26.8% (Fig. 1A). Similarly, in VOYAGE 2, the PASI 90 and PASI 100 responses at week 100 (72.1% and 26.5%, respectively) were maintained through week 252 (80.6% and 38.7%, respectively) (Fig. 1B). The PASI responses for patients treated with adalimumab who crossed over to guselkumab were also maintained over time in both VOYAGE 1 and VOYAGE 2 and were generally comparable to the responses in the guselkumab group (Fig. 1A, B).

Similar responses were observed for IGA scores based on the prespecified TFR analysis. An IGA score of 0/1 at weeks 100 and 252 was achieved by 74.6% and 64.3% of patients, respectively, in VOYAGE 1, and by 80.9% and 87.1% of patients in VOYAGE 2 (Fig. 1C, D). The proportion of patients achieving an IGA score of 0 in the guselkumab group at weeks 100 and 252 was 41.3% and 26.8%, respectively, in VOYAGE 1, and 39.7% and 45.2% in VOYAGE 2 (Fig. 1C, D). IGA scores for patients treated with adalimumab who crossed over to guselkumab were also maintained over time in both VOYAGE 1 and VOYAGE 2, and were generally comparable to responses in the guselkumab group.

Non-responder Imputation and As-Observed Analyses

PASI and IGA outcomes were also analyzed using NRI in VOYAGE 1 and the as-observed methodology through week 252 in VOYAGE 1 and VOYAGE 2. Compared to the prespecified TFR analysis, the proportions of patients achieving PASI 90, PASI 100, an IGA score of 0/1 and an IGA score of 0 at week 252 were similar for the as-observed analyses in both VOYAGE 1 (78.2%, 27.3%, 65.5%, 27.3%, respectively) and VOYAGE 2 (80.6%, 38.7%, 87.1%, 45.2%, respectively), and were slightly lower when the NRI rules were considered in VOYAGE 1 (67.2%, 23.4%, 56.3%, 23.4%, respectively); see Fig. 2A, B. In both analyses, the response rates remained generally stable over time. NRI and as-observed analyses for patients treated with adalimumab who crossed over to guselkumab also showed a similar pattern.

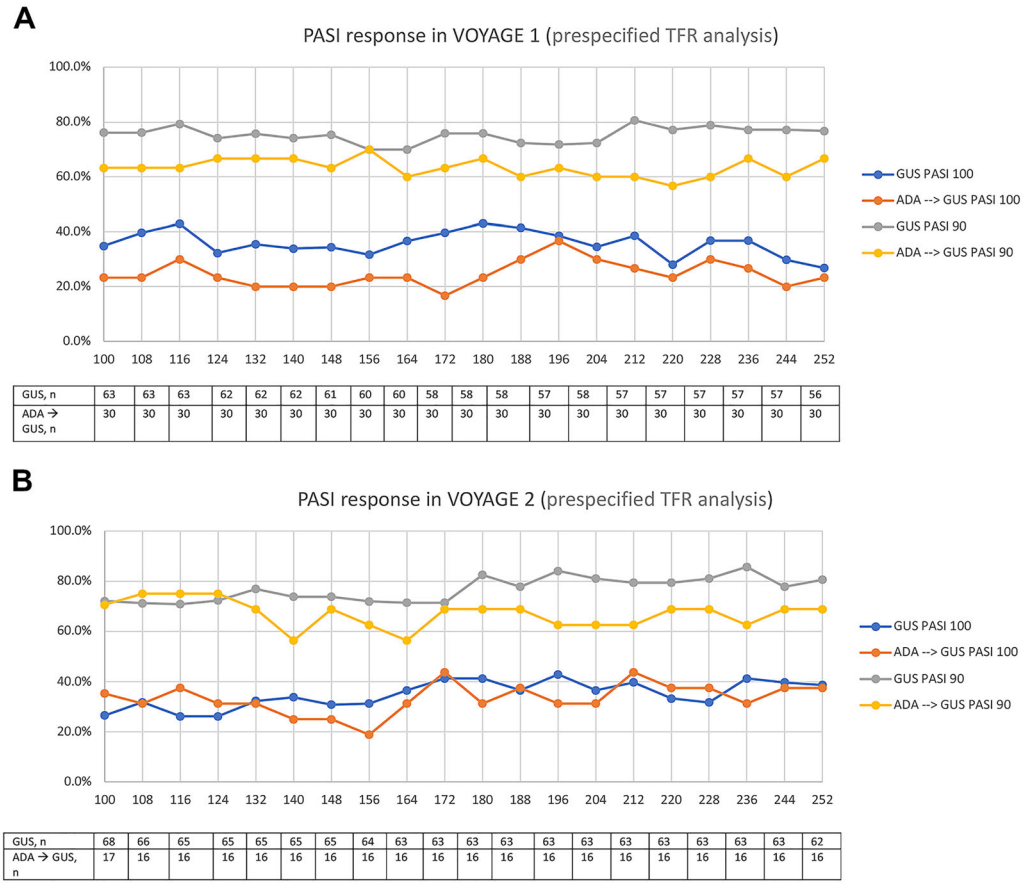


Fig. 1 Clinical response by treatment group through week 252 across VOYAGE 1 and VOYAGE 2 (prespecified TFR analysis). **A** PASI 90 and PASI 100 response in VOYAGE 1. **B** PASI 90 and PASI 100 response in VOYAGE 2. **C** IGA scores of 0/1 (cleared/minimal) and 0 (cleared) in VOYAGE 1. **D** IGA scores of 0/1 and 0 in VOYAGE 2. *In the prespecified analysis, patients who met TFR (defined as discontinuation due to lack of efficacy, worsening of psoriasis, or the use of a protocol-prohibited psoriasis treatment) were considered non-responders. *ADA* adalimumab, *GUS* guselkumab, *IGA* Investigator's Global Assessment, *PASI* Psoriasis Area and Severity Index, *TFR* treatment failure rules

Patient-Reported Outcomes

Patient-reported outcomes (DLQI score 0/1 and 0) substantiated the improvements in clinical responses to guselkumab (Table 2). In the guselkumab group, DLQI scores of 0/1 at weeks 100 and 252, respectively, were achieved by 53.2% and 52.7% of patients in VOYAGE 1, and by 47.1% and 61.3% of patients in VOYAGE 2. The proportion of patients achieving a DLQI of 0 in the guselkumab group at weeks 100 and 252, respectively, was 30.6% and 32.7% in VOYAGE 1 and 36.8% and 40.3% in VOYAGE 2. The mean (standard deviation) change from baseline DLQI score at weeks 100 and 252, respectively, was −15.0 (7.29) and −15.3 (7.49) in VOYAGE 1 and −14.8 (6.73) and −14.7 (6.93) in VOYAGE 2. DLQI scores for patients treated with adalimumab who crossed over to guselkumab were also maintained over time in both VOYAGE 1 and VOYAGE 2 and were generally comparable to responses in the guselkumab group. Of note, at week 252, a larger proportion of patients in the guselkumab group had a DLQI score of 0/1 than in the crossover group: 52.7%% vs 40.0% (VOYAGE 1), and 61.3% vs 37.5% (VOYAGE 2).

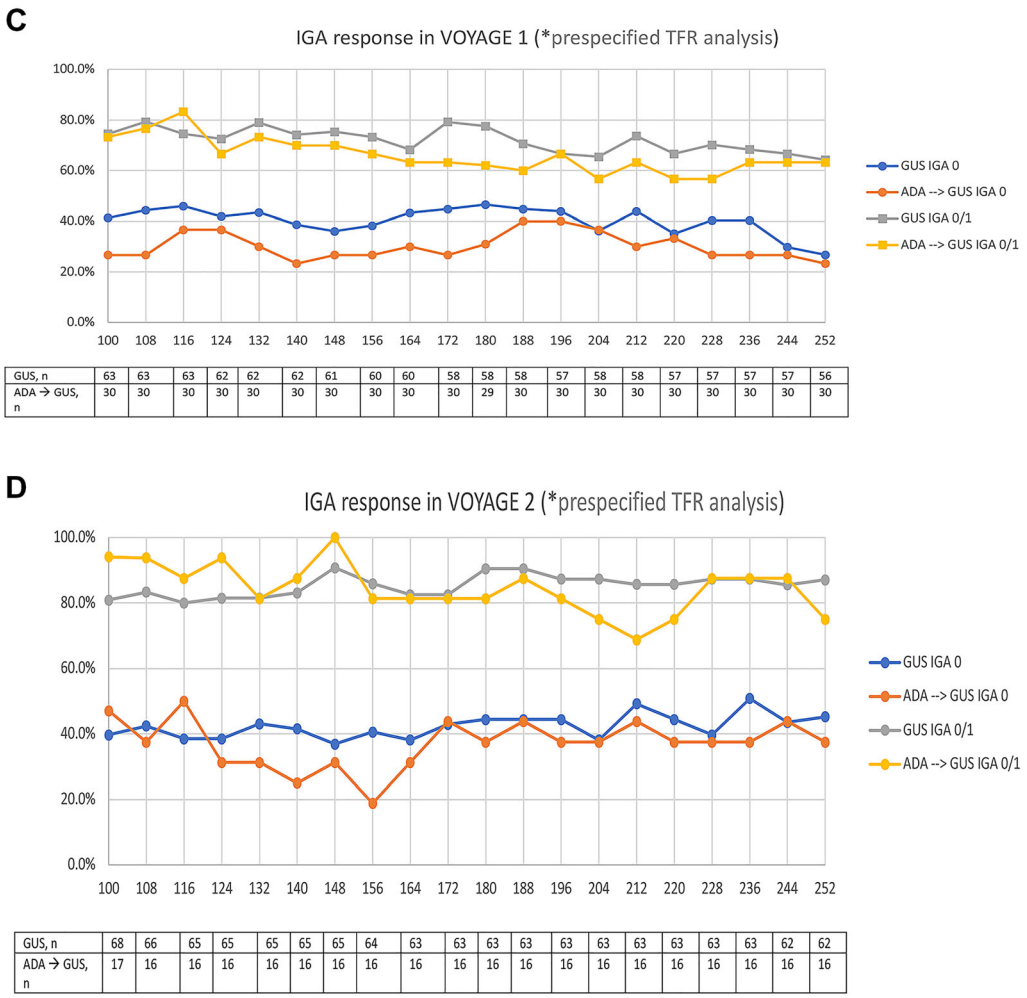


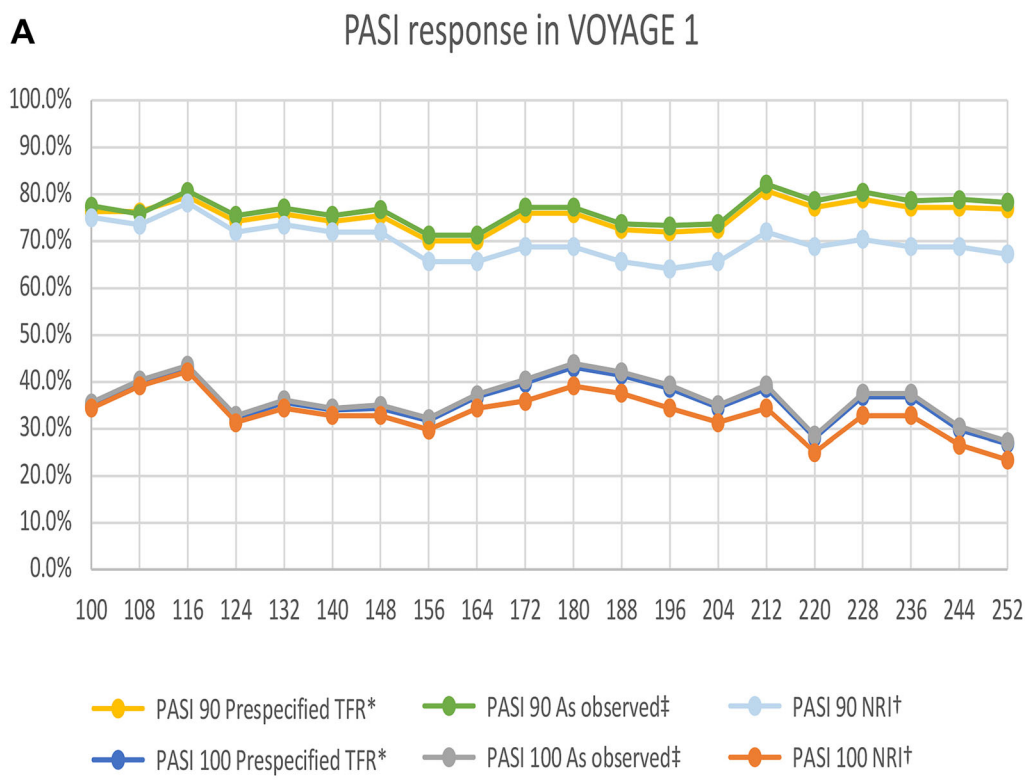
Fig. 1 continued

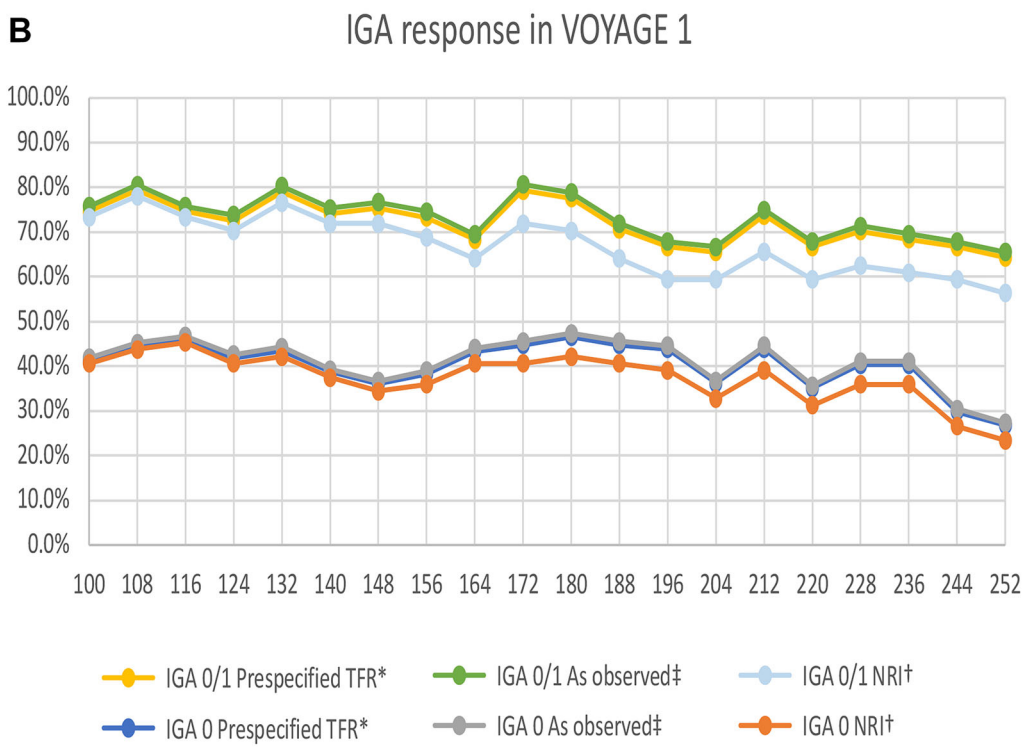
Safety Outcomes

Asian patients were followed for a total of 814 patient-years (PY). The AE rate per 100 PY was 148.08/100 PY (95% CI 139.84, 156.68) across studies, and the number of discontinuations due to AEs was 0.74/100 PY (95% CI 0.27, 1.60). The rate of serious AEs was 3.07/100 PY (95% CI 1.99, 4.53). Rates of AEs of interest were low: serious infections, 0.74/100 PY (95% CI 0.27, 1.60); none of the patients experienced NMSC; malignancies other than NMSC, 0.12/100 PY (95% CI: 0.00, 0.68); no MACE was reported (Table 3). Guselkumab exposure per 100 PY over time also showed a consistent safety profile from year 1 through year 5 for all AEs of interest. The safety profile for guselkumab in the Asian subpopulation was similar to that of the global population: AE rate per 100 PY, 149.0/100 PY (95% CI: 147.0, 152.0), and rate of serious AEs, 5.01/100 PY (95% CI 4.50, 5.56) [25].

DISCUSSION

In the overall global population, over 75% of all patients from both studies continued treatment through year 5 [23]; for Asian patients treated with guselkumab, over 85% of patients continued treatment through 5 years. This analysis of the Asian subpopulation across both studies


A
PASI response in VOYAGE 1
100.0%
90.0%
80.0%
70.0%
60.0%
50.0%
40.0%
30.0%
20.0%
10.0%
0.0%
100 108 116 124 132 140 148 156 164 172 180 188 196 204 212 220 228 236 244 252
PASI 90 Prespecified TFR*
PASI 90 As observed‡
PASI 90 NRI†
PASI 100 Prespecified TFR*
PASI 100 As observed‡
PASI 100 NRI†


B
IGA response in VOYAGE 1
100.0%
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IGA 0/1 Prespecified TFR*
IGA 0/1 As observed‡
IGA 0/1 NRI†
IGA 0 Prespecified TFR*
IGA 0 As observed‡
IGA 0 NRI†

◀**Fig. 2** Clinical response by analysis type in the guselkumab group through week 252 in VOYAGE 1. **A** PASI 90 and PASI 100. **B** IGA scores of 0/1 (cleared/minimal) and 0 (cleared). *In the prespecified TFR analyses, patients who met TFR (defined as discontinuation due to lack of efficacy, worsening of psoriasis, or the use of a protocol-prohibited psoriasis treatment) were considered non-responders. †In the non-responder imputation analyses, patients with missing efficacy data after the application of TFR were counted as non-responders regardless of the reason for the missing data. ‡In the as-observed analyses, the data available at each visit were used and missing data was not imputed. *IGA* Investigator's Global Assessment, *PASI* Psoriasis Area and Severity Index, *TFR* treatment failure rules

shows maintenance dosing with guselkumab 100 mg every 8 weeks sustained high levels of clinical response in the majority of patients through 5 years.

Treatment effects for IGA and PASI responses at weeks 16 and 24 have previously been shown to be consistent between the Asian and non-Asian populations in VOYAGE 1 and VOYAGE 2 [24]. At week 16, treatment differences between guselkumab and placebo were significant for IGA 0/1 and PASI 90 responses (co-primary endpoints) in both the Asian and non-Asian populations and were comparable between populations [24]. At week 24, treatment with guselkumab was superior to adalimumab for IGA 0/1 and PASI 90, and these responses were comparable between the Asian and non-Asian populations [24].

Based on this current prespecified TFR analysis of VOYAGE 1, over 75% of Asian patients exhibited a durable PASI 90 response, and over 60% presented a durable IGA score of 0/1, with complete skin clearance maintained by over 25% of Asian patients through 5 years without dose escalation (evaluated by PASI 100 or IGA score of 0 assessments). In the prespecified TFR analysis of VOYAGE 2, durable PASI 90 and IGA score of 0/1 responses were exhibited by over 80% and almost 90% of Asian patients, respectively, and complete skin clearance was maintained by 45% (IGA score of 0) and 38% (PASI 100) of Asian patients through 5 years. Applying the more conservative NRI methodology yielded slightly lower response rates compared with both the TFR and as-observed analyses of continual treatment with guselkumab (VOYAGE 1). However, high response rates were maintained through 5 years regardless of the analysis methodology. This attests to the robustness of these data and confirms the durability of guselkumab therapy in the Asian population.

In the global VOYAGE 1 and VOYAGE 2 populations, a PASI 90 response was achieved by 84.1% and 82.0% of guselkumab-treated patients at week 252, respectively; a PASI 100 response was achieved by 52.7% and 53.0% of patients; and an IGA score of 0/1 response was achieved by 82.4% and 85.0% of patients [22, 23]. Except for a numerically higher IGA 0/1 response in VOYAGE 2, the PASI and IGA responses in the Asian population were consistent, albeit pared down for PASI 100 with respect to the global population. This may have been due to the greater proportion of Asian patients with more severe psoriasis at baseline (a higher percentage of BSA involvement, a higher baseline PASI and a higher proportion of patients with a baseline IGA score of 4 [severe]), as well as the greater likelihood of Asian patients having undergone phototherapy and/or systemic therapies compared with non-Asian patients [24].

Consistent with the clinical responses, improvements were maintained in patient-reported HRQoL as measured by DLQI. Previous reports of treatment effects for the DLQI score of 0/1 response in VOYAGE 1 and VOYAGE 2 between guselkumab and placebo treatments and between guselkumab and adalimumab treatments showed a difference between the Asian and non-Asian subpopulations at week 16 [24]. A smaller proportion of the Asian subpopulation achieved a DLQI score of 0/1 response compared to the non-Asian subpopulation, regardless of treatment [24]. A similar trend was observed at week 24, although the treatment differences between guselkumab and adalimumab were comparable between populations [24]. The authors suggested that this may have potentially been due to the higher baseline DLQI in all treatment groups in the Asian subpopulation than in the non-Asian

Table 2 Patient-reported DLQI outcomes across VOYAGE 1 and VOYAGE 2 through week 252

DLQI outcomes	Week 100		Week 156		Week 172		Week 204		Week 228		Week 252	
	GUS*	ADA → GUS†	GUS*	ADA → GUS†	GUS*	ADA → GUS†	GUS*	ADA → GUS†	GUS*	ADA → GUS†	GUS*	ADA → GUS†
VOYAGE 1												
Baseline score > 1, *n*	62	30	60	30	58	30	58	30	57	30	55	30
Score = 0/1, *n* (%)	33 (53.2)	16 (53.3)	36 (60.0)	14 (46.7)	35 (60.3)	16 (53.3)	39 (67.2)	13 (43.3)	36 (63.2)	14 (46.7)	29 (52.7)	12 (40.0)
Score = 0, *n* (%)	19 (30.6)	10 (33.3)	22 (36.7)	8 (26.7)	24 (41.4)	10 (33.3)	24 (41.4)	9 (30.0)	27(47.4)	10 (33.3)	18 (32.7)	9 (30.0)
VOYAGE 2												
Baseline score > 1, *n*	68	17	64	16	62	16	63	16	63	16	62	16
Score = 0/1, *n* (%)	32 (47.1)	9 (52.9)	30 (46.9)	7 (43.8)	31 (50.0)	8 (50.0)	33 (52.4)	9 (56.3)	35 (55.6)	7 (43.8)	38 (61.3)	6 (37.5)
Score = 0, *n* (%)	25 (36.8)	6 (35.3)	22 (34.4)	5 (31.3)	23 (37.1)	6 (37.5)	21 (33.3)	6 (37.5)	23 (36.5)	7 (43.8)	25 (40.3)	6 (37.5)

*Placebo crossover patients were included in the guselkumab column after crossover to guselkumab

†This group includes patients randomly assigned to received adalimumab at baseline who crossed over to receive guselkumab at or after week 52 in VOYAGE 1 and at or after week 28 in VOYAGE 2

ADA adalimumab, *DLQI* Dermatology Life Quality Index, *GUS* guselkumab

Table 3 Average incidence of adverse events in guselkumab-treated Asian patients per 100 patient-years through week 264 by treatment group in VOYAGE 1 and VOYAGE 2 studies

	Guselkumab[a] (Asian subpopulation)	Adalimumab → guselkumab[b] (Asian subpopulation)	Combined guselkumab (Asian subpopulation)
Patients treated with guselkumab, *n*	136	48	184
Total patient-years of follow-up	623	192	814
Adverse events	156.77 (147.09, 166.92)	119.88 (104.89, 136.42)	148.08 (139.84, 156.68)
Adverse events leading to discontinuations	0.96 (0.35, 2.10)	0.00	0.74 (0.27, 1.60)
Infections	53.17 (47.59, 59.21)	41.18 (32.60, 51.32)	50.34 (45.59, 55.46)
Infections requiring treatment	19.11 (15.83, 22.87)	13.55 (8.85, 19.86)	17.80 (15.02, 20.95)
Serious adverse events	3.69 (2.34, 5.54)	1.04 (0.13, 3.77)	3.07 (1.99, 4.53)
Serious infections	0.80 (0.26, 1.87)	0.52 (0.01, 2.90)	0.74 (0.27, 1.60)
Malignancies	0.16 (0.00, 0.90)	0.00	0.12 (0.00, 0.68)
Nonmelanoma skin cancer	0.00	0.00	0.00
Other than nonmelanoma skin cancer	0.16 (0.00, 0.90)	0.00	0.12 (0.00, 0.68)
Major adverse cardiovascular events[c]	0.00	0.00	0.00

Rates are reported as number of events per 100 patient-years (95% confiedence interval) for all adverse events except malignancies, which are reported as number of patients with events per 100 patient-years (95% confidence interval)

[a]Includes patients randomized to guselkumab at baseline and those randomized to placebo at baseline who crossed over to receive guselkumab at week 16 in VOYAGE 1 and VOYAGE 2

[b]Includes patients randomized to adalimumab at baseline who crossed over to receive guselkumab either at week 52 in VOYAGE 1 or at or after week 28 in VOYAGE 2

[c]Major adverse cardiovascular events include cardiovascular death, nonfatal myocardial infarction events, and nonfatal stroke

subpopulation [24]. In the current analysis, the DLQI score of 0/1 response was maintained through 5 years by over 50% of Asian patients in VOYAGE 1 and over 60% of Asian patients in VOYAGE 2. The lower DLQI response in VOYAGE 1 may have been due to a higher level of self-reported psoriatic arthritis at baseline. At year 5, a larger proportion of patients in the guselkumab group had a DLQI score of 0/1 than in the adalimumab crossover group. This is most likely a result of patients in the guselkumab group receiving continuous guselkumab treatment for a longer duration than those in the adalimumab crossover group. Together with the clinical responses, these observations show maintenance of response of guselkumab from the perspectives of both the patient and physician.

In the global population, the safety profile remained consistent and favorable through 5 years of continuous guselkumab treatment. The AE and serious AE rates were 149/100 PY

and 5.01/100 PY, respectively, with low rates of AEs of interest ($\leq$ 0.85/100 PY), including NMSC, malignancies other than NMSC, and MACE [25]. Similar findings were evident for Asian patients, with rates of serious AEs and AEs of interest remaining low through 5 years. There were no reports of malignancies, MACE or deaths through 5 years.

In this study, patients of Asian descent participating at centers located in non-Asian countries were considered non-Asian for a number of reasons. Psoriasis may be associated with an even higher psychosocial burden in Asian countries than in non-Asian countries due to cultural reasons, socioeconomic status, and higher levels of social stigma resulting from misunderstanding and misconceptions [26]. Policy and decision makers in Asia consider psoriasis to be a moderate dermatological condition, placing it lower on healthcare priority lists than in non-Asian countries. The management of psoriasis in Asia is further complicated by the use of traditional and herbal medicines [26].

Both VOYAGE 1 and VOYAGE 2 had high retention rates for patients throughout the 5 years. Rates of discontinuation through week 252 were very low for patient populations in both VOYAGE 1 (global 19.6%; Asian 9.6%) and VOYAGE 2 (global 23.4%; Asian 13.3%), indicating that discontinuations were not a major issue in these studies [23]. Furthermore, a proactive approach was taken to address missing data in the prespecified analyses by assigning non-responder status to patients who discontinued the study agent due to lack of efficacy or worsening of psoriasis, and to those who initiated protocol-prohibited psoriatic medications.

Encouraging findings from two real-life retrospective studies conducted in Italy have confirmed the effectiveness and safety of guselkumab in daily clinical practice up to 3 years [27], and as a potential treatment option in patients who have previously failed on anti-IL-17 therapy [15]. How these real-life findings translate to Asian patients with moderate-to-severe psoriasis is worthy of future studies, as is the advancement of personalized medicine in tailoring biologics to these individuals with psoriasis [14].

Limitations of this post-hoc analysis include the lack of blinding and comparator arms during the extension period of both studies. While this may have led to reporting bias, the various analyses conducted minimize this potential limitation, and so these data provide a valuable insight into the ongoing effects of long-term guselkumab treatment for psoriasis in the Asian population.

CONCLUSION

These data through 5 years of continuous treatment with guselkumab in the VOYAGE 1 and VOYAGE 2 trials confirm the favorable benefit–risk profile of this agent in Asian patients with moderate-to-severe psoriasis. Continued responses over 5 years indicate therapeutic longevity for Asian patients requiring long-term treatment for this chronic condition.

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Data Availability. The data sharing policy of Janssen Pharmaceutical Companies of Johnson & Johnson is available at https://www.janssen.com/clinical-trials/transparency. As noted on that site, requests for access to the datasets generated during and/or analyzed during the current study can be submitted through the Yale Open Data Access (YODA) Project site at http://yoda.yale.edu.

Declarations

Conflicts of Interest. Byung Soo Kim has served as a scientific adviser, a clinical study investigator and/or a speaker for AbbVie, Astellas, Boehringer Ingelheim, Bristol Myers Squibb, Celltrion, Eli Lilly, Galderma, GlaxoSmithKline, Janssen, Kyowa Hakko Kirin, LEO Pharma, Novartis, Regeneron, Samsung, Sanofi and UCB. Seong-Jin Jo has conducted clinical trials for, acted as a consultant for, or received speaker's honoraria from AbbVie, Boehringer Ingelheim, Bristol Myers Squibb, Daewoong, Janssen, LEO Pharma, Lilly, Novartis, Pfizer and Sanofi. SangWoong Youn served as a speaker for AbbVie, Cellgene, Eli Lilly, Janssen, LEO Pharma, Novartis and Pfizer organised psoriasis symposium or meetings, and has also performed phase III clinical trials sponsored by Janssen, Novartis, Boehringer Ingelheim, BMS, Eli Lilly, Kyowa Kirin and UCB and phase IV clinical trials sponsored by CKD Pharma, Janssen and LEO Pharma. Kristian Reich has served as a paid advisor and/or a paid speaker for and/or participated in clinical trials (site received patient fees, received fees if acting as a coordinating investigator) sponsored by AbbVie, Affibody, Almirall, Amgen, Biogen-Idec, Boehringer Ingelheim Pharma, Celgene, Covagen, Forward Pharma, Fresenius Medical Care, Galderma, GlaxoSmithKline, Janssen, Janssen-Cilag, Kyowa Kirin, Leo, Eli Lilly, Medac, Merck Sharp & Dohme, Miltenyi, Novartis, Ocean Pharma, Pfizer, Samsung Bioepis, Sanofi, Takeda, UCB Pharma, Valeant and Xenoport. Carine Saadoun, Chia-Ling Chang and Ya-Wen Yang are employees of Janssen Pharmaceutical Companies of Johnson & Johnson. Yu-Huei Huang has conducted clinical trials while serving as a principal investigator for AbbVie, Galderma, Eli Lilly, Janssen-Cilag Pharmaceutica, Novartis Pharmaceuticals Corporation and Pfizer and has received honoraria for serving as an advisory board member for and speaking fees from AbbVie, Celgene, Eli Lilly, Janssen-Cilag Pharmaceutica, Novartis Pharmaceuticals Corporation and Pfizer Limited. Tsen-Fang Tsai has conducted clinical trials or received honoraria for serving as a consultant for Abbvie, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli-Lilly, Galderma, GSK, Janssen-Cilag, Leo Pharma, Merck Sharp & Dohme, Novartis International, Pfizer, PharmaEssentia, Sanofi, and UCB Pharma.

Ethical Approval. This article is based on previously conducted studies (VOYAGE 1 and VOYAGE 2) and does not contain any new studies with human participants performed by any of the authors. Both VOYAGE 1 and VOYAGE 2 were conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki and are consistent with Good Clinical Practices. The study protocols were approved by institutional review boards or independent ethics committees. All participants provided written informed consent.

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