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ORIGINAL ARTICLE

Continuous treatment with guselkumab maintains clinical responses through 4 years in patients with moderate-to-severe psoriasis: results from VOYAGE 1

Christopher E. M. Griffiths[a], Kim A. Papp[b], Michael Song[c], Megan Miller[c], Yin You[c], Yaung-Kaung Shen[c], Chenglong Han[c] and Andrew Blauvelt[d]

[a]Dermatology Centre, Salford Royal Hospital, University of Manchester, NIHR Manchester Biomedical Research Centre, Manchester, UK; [b]K Papp Clinical Research and Probity Research, Inc, Waterloo, Canada; [c]Janssen Research & Development, LLC, Spring House, PA, USA; [d]Oregon Medical Research Center, Portland, OR, USA

ABSTRACT

Objectives: To evaluate the efficacy of guselkumab through four years of continuous treatment for psoriasis.

Methods: In the phase 3 VOYAGE 1 trial, 837 patients with moderate-to-severe psoriasis were randomized to receive guselkumab 100 mg every-8-weeks, placebo, or adalimumab 40 mg every-2-weeks. Patients in the placebo and adalimumab groups crossed over to receive guselkumab at weeks 16/52, respectively; eligible patients received open-label guselkumab through week 204. Efficacy endpoints (i.e., PASI 75/90/100, IGA 0/1, and IGA 0) were analyzed in the guselkumab group using different methodologies: prespecified treatment failure rules (TFR, patients discontinued due to lack of efficacy, psoriasis worsening, or protocol-prohibited psoriasis treatment considered nonresponders); nonresponder imputation (NRI, patients with missing data counted as nonresponders); and As Observed (OBS, no imputation). Safety was evaluated through week 204.

Results: At week 204, PASI 90 response rates were 82.2%, 68.4%, and 84.3%, respectively, based on TFR, NRI, and OBS analyses; corresponding proportions at week 52 were 79.7%, 75.5%, and 80.6%. Similarly, PASI 75, PASI 100, IGA 0/1, and IGA 0 responses were maintained from week 52 through week 204. No new safety signals were identified.

Conclusions: High efficacy response rates were maintained through four years of continuous guselkumab treatment for psoriasis.

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Biologics; guselkumab; long-term; maintenance of response; psoriasis

Introduction

Psoriasis is an immune-mediated, inflammatory disease that, owing to its chronic nature, requires long-term treatment to maintain control. Thus, it is important to observe therapies for long periods of time to allow collection of longitudinal treatment data for adults with psoriasis. Clinical trials of psoriasis treatments with open-label extensions are designed to meet this need. Among several cytokines identified as central to the pathogenesis of inflammatory diseases, interleukin (IL)-23 has been identified as a central driver of psoriasis (1). Guselkumab (CNTO 1959; Janssen Research & Development, LLC, Spring House, PA) was the first interleukin-23 blocker approved for the treatment of moderate-to-severe plaque psoriasis worldwide, including in the United States, Canada, the European Union, and Japan (2). As of December 31 2019, the estimated clinical worldwide exposure to guselkumab since launch is 57,372 person-years (3). Overall, an estimated 3710 patients with psoriasis have been exposed to guselkumab in clinical trials.

The VOYAGE 1 study, which focuses on continuous treatment with guselkumab, is part of a comprehensive clinical development program in psoriasis that also includes other phase 3 trials (4). VOYAGE 2 evaluated randomized withdrawal from guselkumab and NAVIGATE assessed switching from ustekinumab to guselkumab, while the ECLIPSE trial compared guselkumab with secukinumab (5–7). On-going analyses of data from the two VOYAGE trials have established the efficacy and safety of guselkumab for up to three years during which patient retention rates remained high (>80%) (8–11). Here, we report the results from VOYAGE 1 for up to four years of continuous treatment with guselkumab, including patients who were initially randomized to guselkumab as well as those who switched from placebo or adalimumab to guselkumab.

Methods

Study design and patients

Detailed descriptions of the study have been presented previously (4,8). Briefly, VOYAGE 1 (NCT02207231) is an on-going, phase 3, randomized, double-blinded, placebo- and active comparator-controlled trial that was conducted to evaluate the long-term efficacy and safety of guselkumab for the treatment of moderate-to-severe psoriasis. Adult patients (aged ≥18 years)

CONTACT Andrew Blauvelt ablauvelt@oregonmedicalresearch.com Oregon Medical Research Center, 9495 SW Locust St., Suite G, Portland, 97223, OR, USA

were eligible for enrollment in the VOYAGE 1 study if they had an Investigator's Global Assessment (IGA) score of at least 3, a Psoriasis Area and Severity Index (PASI) of at least 12, and percent body surface area involvement with psoriasis of at least 10% for at least 6 months. In addition to having moderate-to-severe psoriasis for at least 6 months, they had to be candidates for systemic therapy or phototherapy.

The study consisted of the blinded treatment period, which comprised the placebo-controlled period (weeks 0–16) and the active comparator-controlled period (weeks 0–48; guselkumab versus adalimumab), and the open-label extension period (starting at week 52 and on-going). At baseline, 837 patients were randomized (2:1:2) to receive either (1) guselkumab 100 mg at weeks 0, 4, and 12 and then every-8-weeks; (2) placebo at weeks 0, 4, and 12 with crossover to guselkumab 100 mg at weeks 16/20 and then every-8-weeks; or (3) adalimumab 80 mg at week 0, 40 mg at week 1 followed by every-2-week dosing through week 47, with crossover to guselkumab 100 mg every-8-weeks at week 52 (adalimumab→guselkumab). Starting at week 52, all eligible patients continued open-label guselkumab treatment every-8-weeks through week 204.

Outcome measures

Disease severity was evaluated by clinicians using two instruments to assess induration, erythema, and scaling of psoriatic lesions: the static IGA (range, 0 [cleared] to 4 [very severe]) and PASI (range 0–72; higher score indicates more severe disease) (12). The impact of skin disease on the patient's life was self-reported using the Dermatology Life Quality Index (DLQI), with scores ranging from 0 (no effect of psoriasis) to 30 (extremely large effect) (13). Patient-reported symptoms and signs of psoriasis were assessed using the Psoriasis Symptoms and Signs Diary (PSSD), with a summary score of 0 indicating no symptoms or signs of psoriasis (14,15). Safety was monitored by collecting information on adverse events (AEs) and monitoring laboratory tests among treated patients.

Statistical analyses

Efficacy endpoints included the proportions of patients achieving at least 75% improvement in PASI from baseline (PASI 75), at least 90% improvement in PASI from baseline (PASI 90), 100% improvement in PASI (PASI 100), IGA score of 0 or 1 (IGA 0/1), and IGA score of 0 (IGA 0) in the guselkumab and adalimumab→guselkumab groups. The guselkumab group was defined as patients randomized to guselkumab at baseline and those randomized to placebo at baseline who crossed over to receive guselkumab at week 16, while the adalimumab→guselkumab group included patients randomized to adalimumab at baseline who crossed over to receive guselkumab at week 52. The first PASI and IGA assessments during the open-label extension period occurred at week 52; the last assessments occurred at week 204.

In the prespecified analyses of PASI and IGA, efficacy was analyzed using treatment failure rules (TFRs). Treatment failure rules were applied for patients who discontinued study agent due to the lack of efficacy or an adverse event of worsening of psoriasis or who started a protocol-prohibited medication/therapy that could improve psoriasis. A patient who met a treatment failure criterion was considered a non-responder for PASI and IGA endpoints from that point onward. In addition, after the TFRs were applied, no imputation was performed for missing data. Sensitivity analyses were conducted to compare PASI and IGA response based on nonresponder imputation (NRI; patients with missing data for any reason were considered non-responders) and As Observed (OBS; no data were imputed) methodologies with the pre-specified analyses.

The pre-specified analyses of patient-reported outcomes included proportions of patients achieving DLQI 0/1 (no effect of psoriasis on patient's life) and proportions of patients achieving PSSD summary scores = 0 (PSSD Symptom = 0, PSSD Sign = 0; no symptoms or signs of psoriasis). The first DLQI and PSSD assessments during the open-label extension period occurred at week 76.

Safety data were summarized for patients receiving at least one dose of guselkumab. Rates of adverse events, including adverse events of interest, were summarized for the guselkumab group (including placebo crossovers) and the adalimumab→guselkumab group through week 204.

Results

Patient characteristics

At baseline, demographic and disease characteristics were comparable across the guselkumab, adalimumab, and placebo treatment groups. The mean age was 43.7 years, most patients were white (81.7%), and the mean body mass index was 29.6. The median PASI was 19.0 (interquartile range, 15.40–25.40), and 99.7% of patients had a moderate or severe IGA score. Additionally, there were no meaningful between-group differences in patient-reported outcomes, including DLQI (mean, 14.0 [range, 0–30]) or PSSD summary scores (mean, 53.0 and 56.9 for symptoms and signs, respectively [range 0–100]). Overall, through 4 years, 191 patients discontinued study agent, with the most common reason being patient withdrawal (i.e. including miscellaneous categories not related to efficacy or safety, such as work/travel schedule, marriage/family commitments, relocation, or pregnancy planning; $n = 51$). The proportions of patients who discontinued guselkumab through week 204 were similar in the guselkumab (21.5%; 108/503) and adalimumab→guselkumab (24.9%; 83/334) groups (Figure 1).

Clinical response

Clinical responses were maintained with continuous guselkumab treatment during the open-label extension period. In the guselkumab group, the PASI 75, 90, and 100 response rates were similar between week 52 (93.8%, 79.7%, and 49.1% respectively) and week 204 (93.4%, 82.2%, and 55.7%, respectively) (Figure 2(a–c)). Similarly, the proportions of patients achieving IGA 0/1 and IGA 0 at week 52 (84.6% and 53.6%, respectively) were comparable to those at week 204 (81.7% and 57.1%, respectively) (Figure 2(d,e)). Following crossover to guselkumab at week 52, PASI and IGA responses in the adalimumab→guselkumab group were similar to those in the guselkumab group through week 204: PASI 75, PASI 90, PASI 100, IGA 0/1, IGA 0 at week 52 (72.4%, 50.5%, 24.0%, 60.4%, and 27.3%) and week 204 (94.1%, 82.0%, 52.0%, 81.6%, and 53.1%) (Figure 2(a–e)).

Regardless of the analysis method used, clinical responses in the guselkumab group were maintained from week 52 through week 204 (Figure 3). As expected, rates based on the most

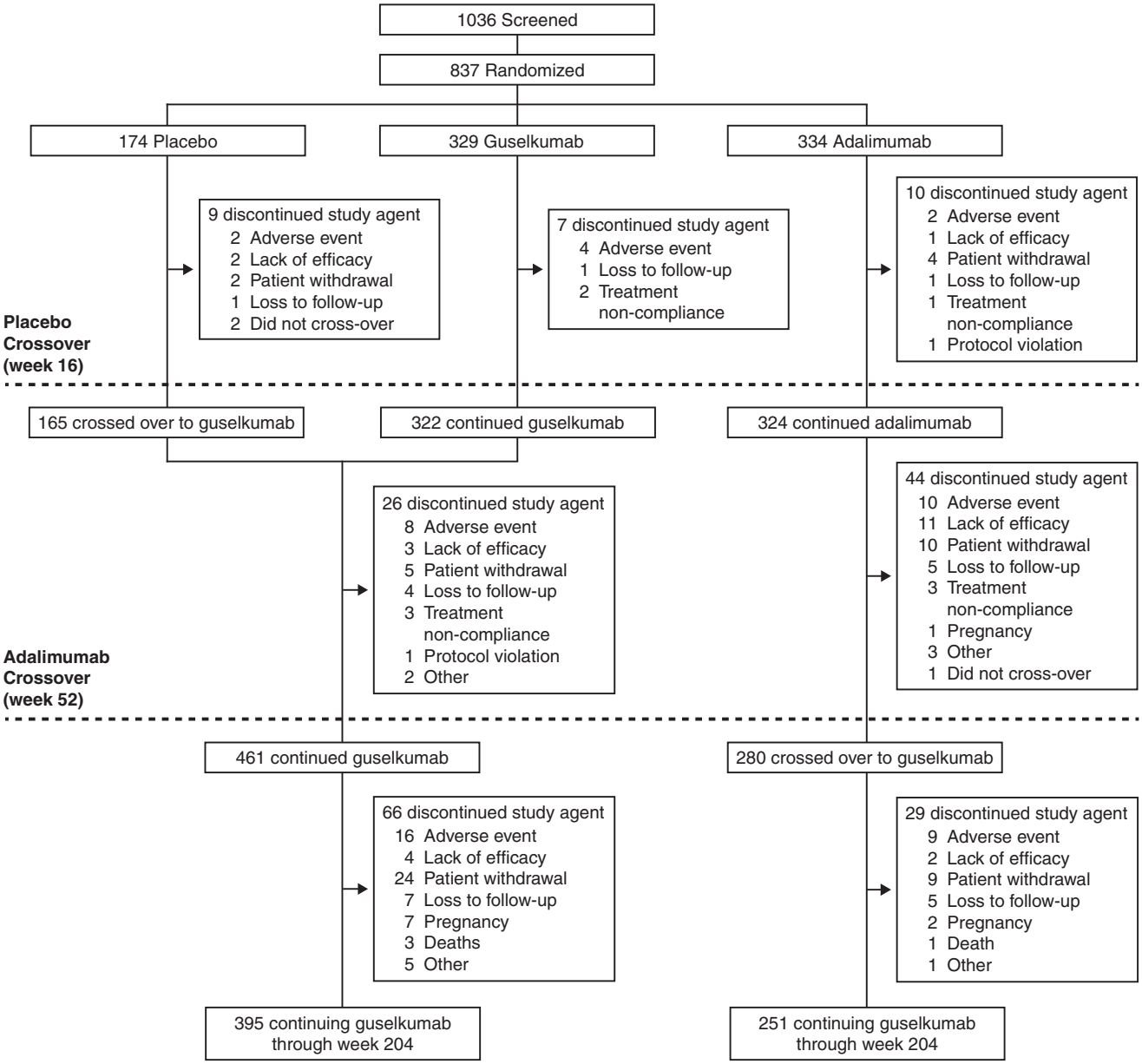


Figure 1. Patient disposition in the guselkumab and adalimumab→guselkumab groups from baseline through week 204.

conservative NRI method were lower than those based on the TFR and OBS methods. At week 204, PASI 90 response rates in the guselkumab group were 82.2%, 68.4%, and 84.3%, respectively, based on TFR, NRI, and OBS analyses. Trends were similar for the other assessments, including PASI 75, PASI 100, IGA 0/1, and IGA 0 (Figure 3).

Absolute PASI responses (PASI = 0, >0 and ≤1, >1 and ≤3, >3 and ≤5, and >5) were maintained from week 52 through week 204 (Figure 4(a)). Approximately half of all patients in the guselkumab group achieved complete clearance (absolute PASI = 0) over time: 49.1%, 51.1%, 50.9%, and 55.7% at weeks 52, 100, 156, and 204, respectively. In general, the proportions of patients with PASI >0 and ≤1, > 1 and ≤3, or >3 and ≤5 decreased over time. Absolute PASI responses in the adalimumab→guselkumab group were similar to those in the guselkumab group from week 100 (after crossover from adalimumab to guselkumab at week 52) through week 204 (Figure 4(b)).

Patient-reported outcomes

Improvements in patient-reported outcomes observed over time were consistent with PASI and IGA clinical responses. The proportion of patients achieving DLQI 0/1 (no effect of psoriasis on patient's life) remained consistent from week 76 through week 204 in both treatment groups (Figure 5). In the guselkumab group, DLQI 0/1 was achieved by 75.7% at week 76 and 75.3% at week 204. Likewise, the proportions of patients achieving PSSD symptom and sign summary scores of 0 were sustained from week 76 to week 204 (Figure 6). PSSD symptom-free status was achieved by 39.2% and 42.5% of patients in the guselkumab group at weeks 76 and 204, respectively; corresponding rates for sign-free status were 29.4% and 33.2%. Compared with the guselkumab group, similar proportions of patients in the adalimumab→guselkumab group achieved DLQI 0/1 and PSSD Summary scores = 0 from week 76 through week 204.

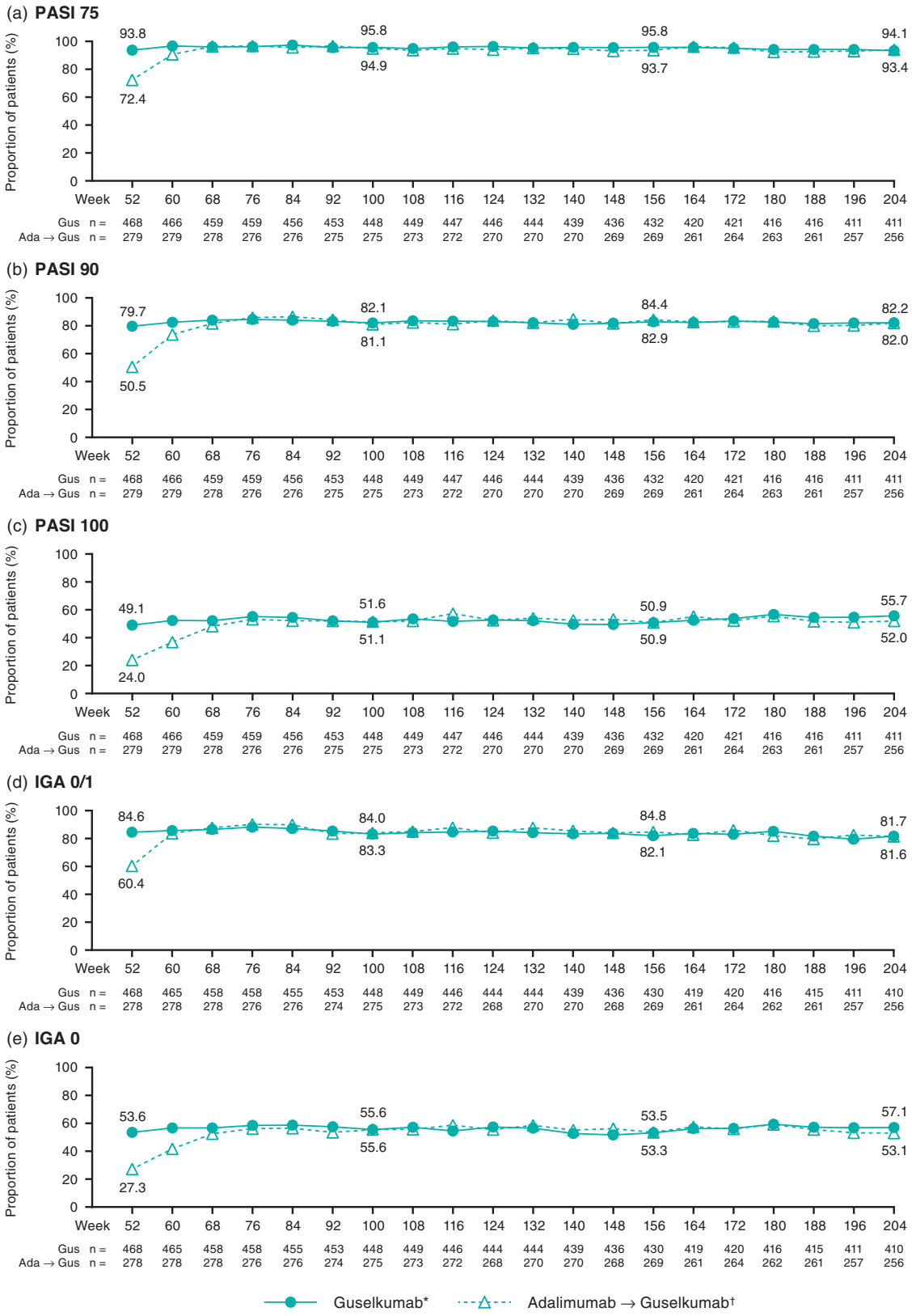
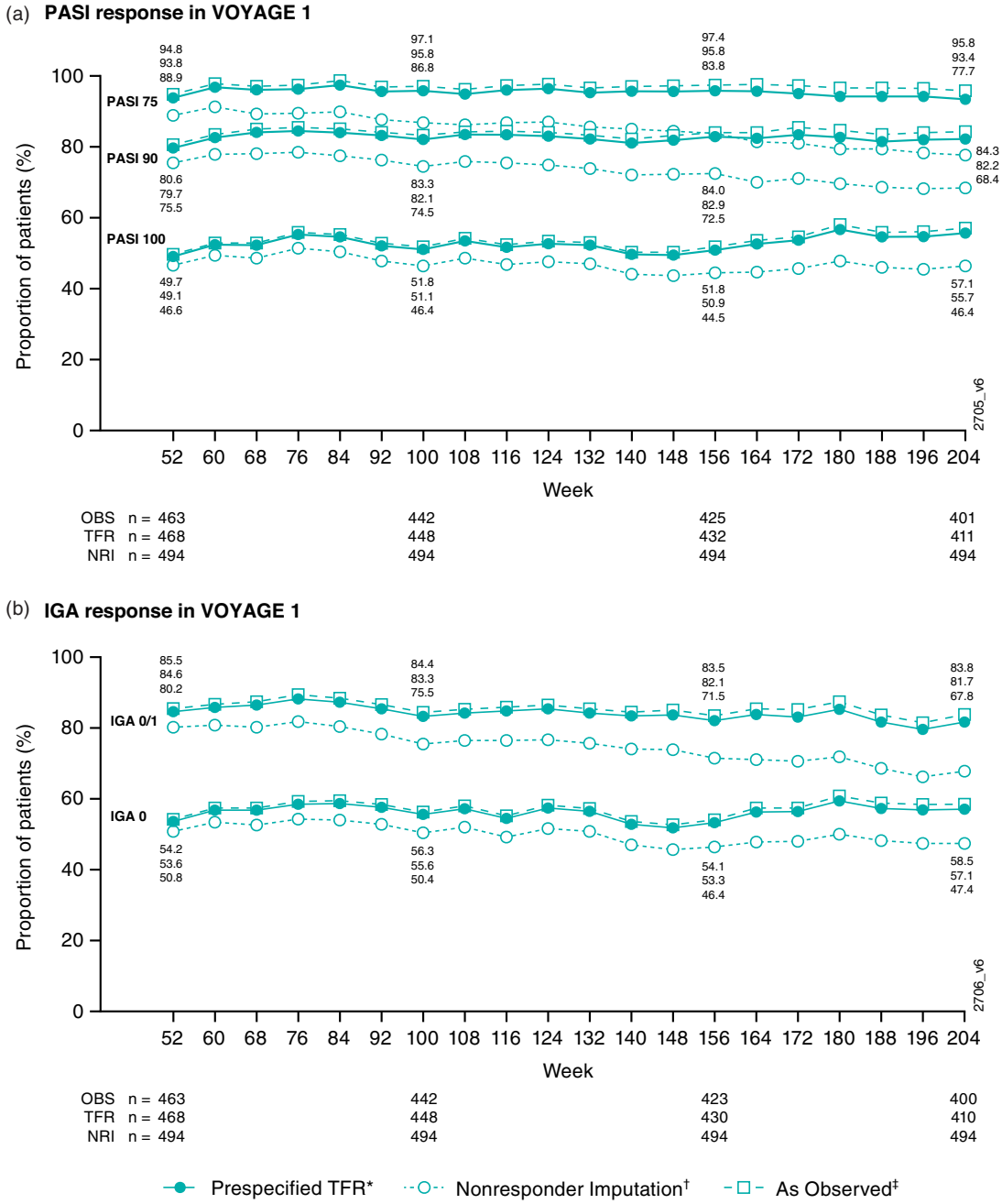


Figure 2. Proportion of patients achieving clinical response by treatment group in the guselkumab and adalimumab→guselkumab groups from week 52 through week 204: (a) PASI 75, (b) PASI 90, (c) PASI 100, (d) IGA 0/1, and (e) IGA 0. Note: The analysis was performed using observed data after applying treatment faliure rules. *Includes patients randomized to guselkumab at baseline and those randomized to placebo at baseline who crossed over to receive guselkumab starting at week 16. †Includes patients randomized to adalimumab at baseline who crossed over to receive guselkumab at week 52. Ada→Gus, Adalimumab→Guselkumab; Gus, Guselkumab; IGA 0/1 and IGA 0, score of cleared/minimal and cleared on the investegator's Global. Assessment; PASI 75, PASI 90, PASI 100, ≥75%, ≥90%, and 100% improvement from baseline in Psoriasis Area and Severity Index.



* In the Prespecified TFR analyses, patients who met TFR (defined as discontinuation due to lack of efficacy, worsening of psoriasis, or use of protocol-prohibited psoriasis treatment) were considered as nonresponders.

† In the Nonresponder Imputation analyses, patients with missing efficacy data after application of TFR were counted as nonresponders regardless of the reason for missing data.

‡ In the As Observed analyses, data available at each visit were used and missing data was not imputed.

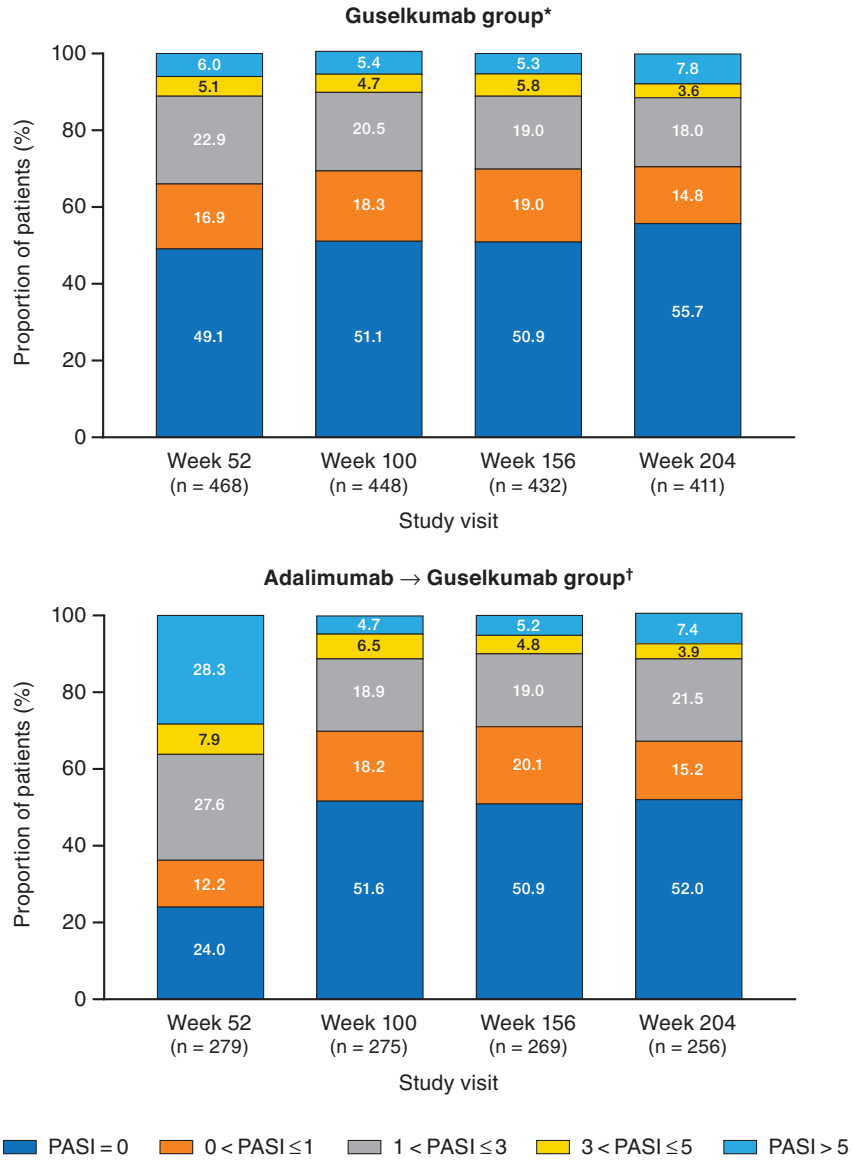
IGA, Investigator's Global Assessment; IGA 0, IGA score of cleared; IGA 0/1, IGA score of cleared or minimal; NRI, nonresponder imputation; OBS, as observed; PASI, Psoriasis Area and Severity Index; PASI 75, ≥75% improvement in PASI; PASI 90, ≥90% improvement in PASI; PASI 100, 100% improvement in PASI; TFR, treatment failure rules.

Figure 3. Proportion of patients achieving clinical response by analysis method (TFR, NRI, OBS) in the guselkumab group from week 52 through week 204: (a) PASI 75, PASI 90, and PASI 100, and (b) IGA 0/1 and IGA 0.

Safety

Safety was assessed in 774 patients receiving at least one dose of guselkumab for a mean duration of 166.95 weeks. Cumulative rates of adverse events, discontinuations due to adverse events, and serious adverse events were generally comparable between the guselkumab and the combined guselkumab groups. Rates of adverse events of interest, including serious infections, malignancies, and major adverse cardiovascular events were low (Table 1); no new safety concerns were observed.

Through week 204, five deaths were reported in patients receiving guselkumab (i.e., completed suicide, epiglottic cancer, liver failure, and astrocytoma in the guselkumab group and



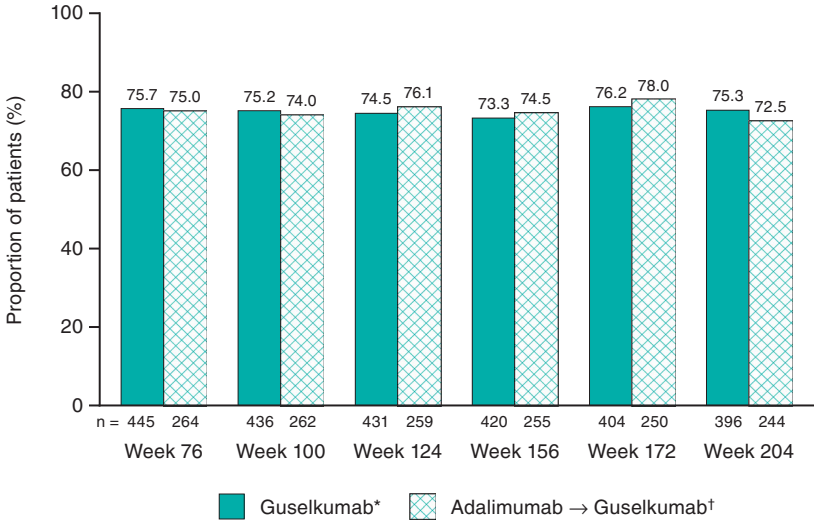
* Includes patients randomized to guselkumab at baselline and those randomized to placebo at baseline who crossed over to receive guselkumab starting at week 16.
† Includes patients randomized to adalimumab at baseline who crossed over to receive guselkumab at week 52.
PASI, Psoriasis Area and Severity Index

Figure 4. Proportion of patients achieving absolute PASI response thresholds from week 52 through week 204 in the (a) guselkumab group, and (b) adalimumab→guselkumab group.

stroke in the adalimumab→guselkumab group). Through week 204, no systemic hypersensitivity reactions, including anaphylactic reactions or serum sickness-like reactions, occurred in any guselkumab-treated patient. Overall, rates of candidiasis were low, with specific types occurring in less than 1% of patients ($n = 4$ [0.8%] skin; $n = 2$ [0.4%] oral; $n = 3$ [0.6%] vulvovaginal; and $n = 1$ [0.2%] genital) in the guselkumab group. Incidence rates of neutropenia remained low ($n = 4$ [0.8%] in the guselkumab group); no patients discontinued from study treatment due to neutropenia and all cases resolved. No events of Crohn's disease or ulcerative colitis were reported through week 204. Overall, 26 of 774 guselkumab-treated patients (3.4%) reported injection site reactions (ISRs) and 72 of 16,296 guselkumab injections (0.4%) were associated with ISRs; over 90% of ISRs (65 of 72) were considered mild in intensity.

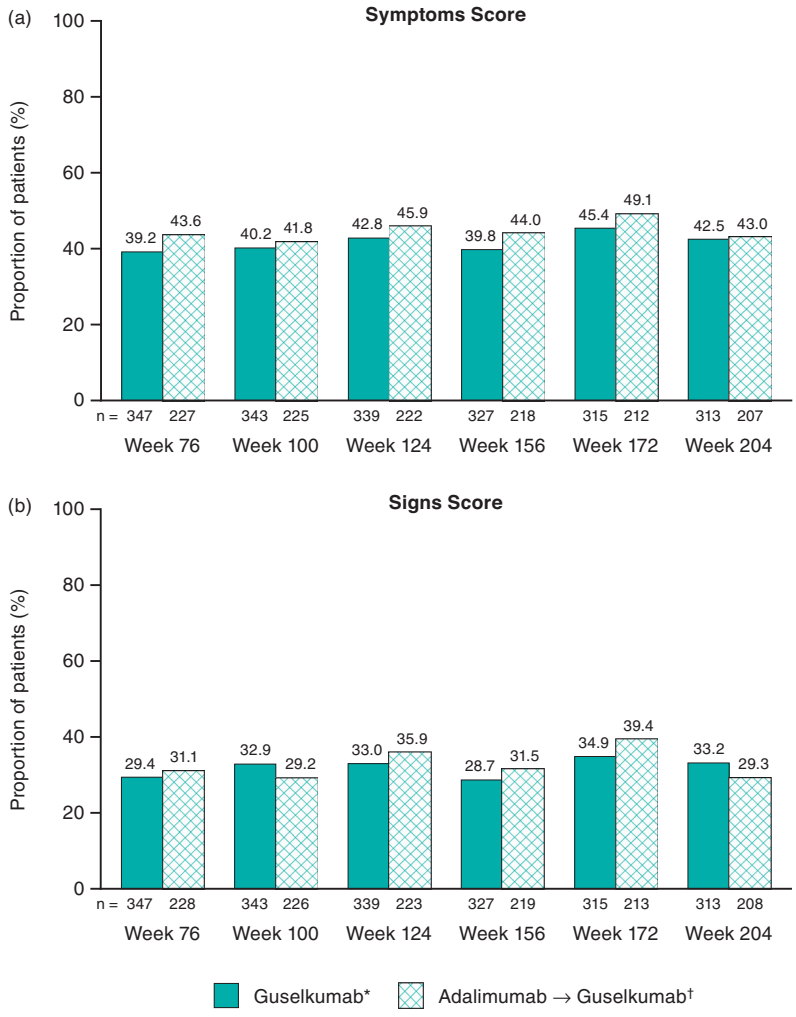
Discussion

Our results show that, with continuous guselkumab treatment in the VOYAGE 1 trial, clinically significant improvements and a favorable safety profile were maintained for up to four years in patients with moderate-to-severe psoriasis. These findings represent data collected over the longest treatment period reported for an IL-23 inhibitor in psoriasis to date. High efficacy response rates were maintained through week 204 of treatment with guselkumab in patients with moderate-to-severe psoriasis (>80% maintaining cleared or minimal psoriasis [PASI 90 and IGA 0/1] and >50% maintaining cleared disease [PASI 100 and IGA 0]). This was true in the guselkumab group, which included placebo crossovers at week 16, as well as the adalimumab→guselkumab group (i.e., randomized to adalimumab at



* Includes patients randomized to guselkumab at baseline and those randomized to placebo at baseline who crossed over to receive guselkumab starting at week 16.
† Includes patients randomized to adalimumab at baseline who crossed over to receive guselkumab starting at week 52.
DLQI, Dermatology Life Quality Index

Figure 5. Proportion of patients achieving DLQI 0/1 in the guselkumab group and the adalimumab→guselkumab group from week 76 through week 204.



* Includes patients randomized to guselkumab at baseline and those randomized to placebo at baseline who crossed over to receive guselkumab starting at week 16.
† Includes patients randomized to adalimumab at baseline who crossed over to receive guselkumab starting at week 52.
PSSD, Psoriasis Symptoms and Signs Diary

Figure 6. Proportion of patients achieving PSSD Summary Scores = 0 in the guselkumab group and adalimumab→guselkumab group from week 76 through week 204: (a) symptoms, (b) signs.

Table 1. Proportion of guselkumab-treated patients reporting safety events through week 204.

	Guselkumab*	Adalimumab→Guselkumab†	Combined Guselkumab‡
Patients treated with guselkumab, n	494	280	774
Average duration of follow-up, weeks	179.03	145.64	166.95
At least one adverse event	437 (88.5)	223 (79.6)	660 (85.3)
Adverse events → discontinuation	29 (5.9)	9 (3.2)	38 (4.9)
Infections	347 (70.2)	173 (61.8)	520 (67.2)
Infections requiring treatment	169 (34.2)	85 (30.4)	254 (32.8)
At least one serious adverse event	82 (16.6)	27 (9.6)	109 (14.1)
Serious infections	15 (3.0)	4 (1.4)	19 (2.5)
Malignancies			
Nonmelanoma skin cancer	8 (1.6)	3 (1.1)	11 (1.4)
Other than nonmelanoma skin cancer	13 (2.6)	2 (0.7)	15 (1.9)§
Major adverse cardiovascular events	3 (0.6)	3 (1.1)	6 (0.8)¥

Data are presented as number of patients (%), unless otherwise indicated.
*Includes patients randomized to guselkumab and those randomized to placebo who crossed over to receive guselkumab starting at week 16.
†Includes patients randomized to adalimumab who crossed over to receive guselkumab starting at week 52.
‡Includes the guselkumab and adalimumab→guselkumab groups, as defined above.
§Includes three breast cancers; two each colorectal cancer, head and neck cancer, melanoma, and prostate cancer; and one each bladder cancer, brain cancer, lymphoma, and sarcoma.
¥Includes four myocardial infarctions and two cerebrovascular accidents, one of which led to death.

baseline and crossed over to receive guselkumab starting at week 52). Analysis of patient-reported outcomes corroborated PASI and IGA clinical results, with approximately three-quarters of patients achieving DLQI 0/1 (no effect at all of psoriasis on patient's life) and over one-third of patients reporting symptom- and sign-free status consistently through week 204.

Compared with response rates presented previously (4,8), response rates in the current study were comparable based on the pre-specified TFR analyses (where patients were counted as nonresponders if they failed specific rules for treatment failure [i.e., discontinued study agent due to lack of efficacy or an adverse event of worsening of psoriasis or if they started a protocol-prohibited medication/therapy that could improve psoriasis]) and the OBS analyses (wherein data were not imputed for any reason). Results of the third analysis method (NRI), which stipulates that missing data are not imputed and that patients with missing data for any reason are counted as nonresponders, indicated slightly lower responses compared with the other two analysis methods. This is not unexpected, as the NRI method counted patients as nonresponders regardless of the reason for discontinuation. In the long-term studies such as VOYAGE 1, patients could discontinue from the study for various reasons unrelated to efficacy; in fact, in our study, the most common reason of discontinuation was patient withdrawal, and additional verification steps were taken during the trial to ensure the discontinuation was not efficacy-related. Therefore, the NRI data may provide the most transparent interpretation of the durability of response over time. While it is difficult to compare data across trials due to differences in study design, treatment dosing, and patient characteristics, our results are comparable to those observed for long-term treatment with other biologics, which may be derived from analyses using less conservative techniques (16–19).

The safety profile of guselkumab remained favorable, with no new signals of concern revealed with longer treatment through four years. While cumulative rates of adverse events increased with time as expected, rates of serious adverse events and targeted adverse events (including serious infections, malignancies, and major adverse cardiovascular events) remained low at week 204 (4,5,8,10,11). This is encouraging, as adverse events that require a longer latency period, such as malignancy, continue to be reported at very low rates – even with four years of treatment.

As with all long-term studies, this study may have been limited by decreased patient retention rates over time. However, the fact that 77% of all patients were continuing study agent for up to four years of follow-up indicates that this was not a fundamental issue in VOYAGE 1. Another limitation was the fact that patients received open-label treatment and no comparator arm was included during the extension period from week 52 through week 204. This may lead to reporting bias, though the various analyses minimize this potential limitation. Nevertheless, these data provide valuable insight into the on-going effect of long-term treatment with guselkumab.

In conclusion, results through four years of continuous treatment with guselkumab in the VOYAGE 1 trial confirm the positive benefit-risk assessment in patients with moderate-to-severe psoriasis. Continued responses over four years indicate therapeutic longevity for patients requiring long-term treatment for their chronic psoriasis.

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ORCID

Christopher E. M. Griffiths http://orcid.org/0000-0001-5371-4427
Kim A. Papp http://orcid.org/0000-0001-9557-3642
Chenglong Han http://orcid.org/0000-0001-7175-7834
Andrew Blauvelt http://orcid.org/0000-0002-2633-985X

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