Efficacy and safety of guselkumab, administered with a novel patient-controlled injector (One-Press), for moderate-to-severe psoriasis: results from the phase 3 ORION study

Laura K. Ferrisa, Elyssa Ottb, Jingzhi Jiangc, H. Chih-Ho Hongd, Shu Lie, Chenglong Hanf, and Wojciech Barangh

aDepartment of Dermatology, University of Pittsburgh, Pittsburgh, PA, USA; bJanssen Scientific Affaits, LLC, Horsham, PA, USA; cJanssen Research & Development, LLC, Fremont, CA, USA; dUniversity of British Columbia, Department of Dermatology and Skin Science and Probitry Medical Research, Surrey, Canada; eJanssen Research & Development, LLC, Spring House, PA, USA; fJanssen Research & Development, LLC, Malvern, PA, USA; gDepartment of Dermatology, Venereology and Allergology, Wroclaw Medical University, Wroclaw, Poland

ABSTRACT

Objectives: Guselkumab, an interleukin-23 antagonist, is approved for self-administration with the UltraSafe Plus™ syringe to treat moderate-to-severe plaque-type psoriasis. We evaluated the efficacy, safety, pharmacokinetics, and acceptability of guselkumab administered using a novel patient-controlled injector (One-Press) in psoriasis patients.

Materials and methods: This Phase 3, multicentre, double-blind, placebo-controlled study (ORION, Clinicaltrials.gov identifier-NCT02905331) randomized adults with moderate-to-severe psoriasis (4:1) to guselkumab 100 mg at Weeks 0/4/12/20/28 or placebo at Weeks 0/4/12 with crossover to guselkumab 100 mg at Weeks 16/20/28. Week 16 co-primary endpoints were the proportions of patients achieving Investigator Global Assessment (IGA) cleared/minimal (IGA 0/1) and Psoriasis Area and Severity Index 90% improvement (PASI90) responses. One-Press usability/acceptability was evaluated using the Self-Injection Assessment Questionnaire (SIAQ) and Patient-Controlled Injection Device Questionnaire. Final assessments occurred at Week 40.

Results: At Week 16, significantly higher proportions of guselkumab-treated (N = 62) than placebo-treated (N = 16) patients achieved IGA 0/1 (80.6% vs. 0.0%, p < .001) and PASI90 (75.8% vs. 0.0%, p < .001) responses. Adverse events were comparable between treatments. SIAQ results demonstrated 99% (68/69) of patients were satisfied/very satisfied with One-Press at Week 28.

Conclusions: Guselkumab administered using the One-Press patient-controlled injector was efficacious and well-tolerated in moderate-to-severe psoriasis patients, consistent with previously reported Phase-3 studies of guselkumab administered using UltraSafe Plus. One-Press was highly acceptable to patients.

Introduction

Biologic agents are highly effective in the treatment of psoriasis. Long-term outcomes, however, are partially dependent on patient adherence. Most biologic agents are self-administered by subcutaneous (SC) injection. While injection with a syringe is mechanically reliable and simple, the inherent difficulty of injecting oneself, along with other factors, can lead to variable compliance (1,2). Autoinjectors have been developed to assist patients with accomplishing what can be a stressful task, and several studies have demonstrated they are associated with good tolerability, patient satisfaction, and success with injection (3–6). As such, it has been suggested that such devices may improve patient adherence (7). However, autoinjectors must rely on proper mechanical function. Malfunction and complexity of use can prevent successful injection (8,9).

Given the need for an improved self-injection device, a novel patient-controlled injector (One-Press) was developed. Guselkumab was previously studied in two pivotal studies (VOYAGE 1 and VOYAGE 2) with the UltraSafe Plus™ syringe (10,11). The UltraSafe Plus requires the patient to deploy the syringe’s plunger to deliver guselkumab, while One-Press incorporates additional usability and safety features that hide the needle from view and has an ergonomic design to facilitate operation. Both employ an identical single-dose prefilled syringe and have design features that reduce the risk of accidental needle sticks. Unlike a traditional autoinjector, One-Press allows the patient to manually control the injection speed in the absence of an automated mechanism.

In this Phase 3 study, we evaluated the efficacy, safety, and pharmacokinetics (PK) of guselkumab compared with placebo, both administered via the One-Press device, for treating moderate-to-severe psoriasis. The similar design of the placebo-controlled portions of the ORION, VOYAGE 1 and VOYAGE 2 studies allows for reasonable comparison of clinical outcomes for guselkumab administered with the UltraSafe Plus and One-Press devices. This study also evaluated acceptability of the One-Press device using the Self-Injection Assessment Questionnaire (SIAQ).
Materials and methods

Study design

ORION (Clinicaltrials.gov identifier: NCT02905331) was a Phase 3, multicentre, double-blind, placebo-controlled study in which patients were centrally randomized (4:1) to receive SC guselkumab 100 mg at Weeks 0, 4, 12, 20, and 28 or SC placebo at Weeks 0, 4, and 12 with crossover to guselkumab 100 mg at Weeks 16, 20, and 28, both delivered by the One-Press patient-controlled injection device. Patients randomized to guselkumab received placebo at Week 16 to maintain the blind. Efficacy was evaluated q4w through Week 32 and again at Week 40, and safety was assessed continuously through Week 40.

Patients

Eligible patients (≥18 years of age) had moderate-to-severe plaque psoriasis (i.e. Investigator Global Assessment [IGA] score ≥3, Psoriasis Area and Severity Index [PASI] score ≥12, body surface area [BSA] involvement ≥10%) for ≥6 months prior to screening, were candidates for systemic therapy or phototherapy, and were willing to self-administer study agents independently. Patients were ineligible if they had a history or current signs of a severe, progressive, or uncontrolled medical condition or had a history (within 5 years) of, or current, malignancy (exclusive of nonmelanoma skin cancer).

Randomization and blinding

Randomization employed a computer-generated permuted block schedule with stratification by country. An interactive web response system assigned a unique treatment code dictating treatment assignment and matching study drug kit. Codes were not provided to investigators. Guselkumab and placebo were delivered by identical devices (see Interventions).

Interventions

Study agent was delivered using the One-Press device housing a single-use prefilled glass syringe with a 27-gauge, half-inch fixed needle containing 1-ml of a sterile solution of guselkumab (100 mg/mL) or placebo (Figure 1). All study drug injections were self-administered by patients at the study site after receiving training on the proper use of the novel device. The first self-injection (Week 0) was observed by site staff.

Assessments

Efficacy

Investigators assessed patient response to treatment using the IGA and PASI assessment tools. The IGA documents the investigator’s assessment of the patient’s psoriasis at a given time point. Overall lesions are graded for induration, erythema, and scaling as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). For the PASI (12), each of four body regions (head, trunk, upper extremities, lower extremities) is independently assessed for the percentage of the area involved, which translates to a numeric score ranging from 0 (no involvement) to 6 (90–100% involvement), and for erythema, induration, and scaling, which are each rated on a scale of 0 (none) to 4 (maximum). Total PASI scores may range from 0 (clear skin) to 72.

Usability and acceptability

Patients completed the SIAQ before the Week-0 injection and after self-injection at Weeks 0, 4, 12, and 28. The SIAQ was developed and validated in patients with rheumatoid arthritis (13) and was employed in a clinical trial of adult patients with moderate-to-severe psoriasis (14). Using the SIAQ, patients rated the acceptability of their experience using the One-Press device across six domains (predose and postdose: feeling about injections, self-confidence, and satisfaction with self-injection; postdose only: self-image, pain and skin reactions during or after the injection, and ease of self-injection device use). Patients rated each domain on a 5- to 6-point semantic Likert-type scale, and ratings were then transformed to scores ranging from 0 (worst experience; equivalent to rating of 1) to 10 (best experience; equivalent to rating of 5 or 6). Patients also completed a questionnaire specific to the One-Press device after all study evaluations were completed, including self-injection of study drug and completion of the postdose module of the SIAQ. Using the Patient-Controlled Injection Device Questionnaire, patients indicated their agreement with each of three statements regarding use of the One-Press device (‘I liked being able to inject the medication at a speed that was comfortable for me,’ ‘The design of the device handle made the device easy to use,’ and ‘I was able to easily tell when the injection was finished’) on a 5-point scale (strongly disagree, disagree, neither agree or disagree, agree, or strongly agree).

PK and immunogenicity

Serum guselkumab concentrations were measured by a validated, specific, and sensitive electrochemiluminescence immunoassay (ECLIA) method using the Meso Scale Discovery (MSD)® platform.

Figure 1. Depiction of the guselkumab One-Press device.
Serum guselkumab concentrations <0.01 µg/mL were below the lower limit of quantification (LLQ). The presence of antibodies to guselkumab in collected blood samples was determined using a sensitive and drug-tolerant ECLIA, also using the MSD platform. Serum samples that tested positive for anti-guselkumab antibodies were further characterized to determine if the antibodies could neutralize the biological activity of guselkumab in vitro, using a validated competitive ligand binding assay based on the MSD ECLIA detection technology.

**Safety**

Safety was primarily assessed by summarizing the incidence and type of adverse events (AEs) and examining changes in clinical laboratory parameters (hematology and chemistry). Injection-site reactions (ISRs) were defined as any unfavorable or unintended sign, including pain, erythema, and/or induration, that occurred at the study drug injection site. In addition to this standard definition for ISRs, study sites were instructed to report an AE of ISR in all cases where patients responded positively (all responses except 'not at all') to 'How bothered were you?' by ISRs in the SIAQ domain of 'Pain and skin reactions during or after the injection.'

**Product quality**

Study sites were instructed to report any instance of dissatisfaction relative to the identity, quality, durability, or reliability of the study drug or injection device to the study sponsor.

**Statistical analyses**

Efficacy analyses employed all randomized patients who received ≥1 injection of study agent, analyzed according to assigned treatment groups (full analysis set). The co-primary endpoints were the proportions of patients achieving IGA 0/1 and PASI90 responses at Week 16. Patients who met treatment failure criteria (discontinued study agent due to lack of efficacy/an AE of worsening psoriasis or started a protocol-prohibited treatment before Week 16) were considered nonresponders for the co-primary endpoints at Week 16, as were patients who did not return for evaluation at Week 16. Protocol-prohibited treatments included topical psoriasis therapies (topical moisturizers/shampoos containing tar/salicylic acid were allowed), systemic corticosteroids used for psoriatic arthritis or psoriasis (intra-articular corticosteroids allowed), any other systemic or biologic psoriatic therapy, and phototherapy for psoriasis. Major secondary endpoints, as assessed at Week 16, were the proportions of patients achieving IGA 0 (clear) and PASI100 responses. The same data handling rules employed for the co-primary endpoints were applied to the major secondary endpoints.

To control for Type 1 error, the primary and major secondary analyses were tested in a fixed sequence, such that if one of the co-primary endpoint comparisons was not significant at a 2-sided α-level of 0.05, the co-primary endpoints to be considered not significant; major secondary endpoints were to be tested only after the co-primary endpoints were met and the second major secondary endpoint was to be tested only if the first one was met. A Fisher’s exact test was employed to compare response rates between the guselkumab and placebo groups. Differences in the proportions of patients achieving responses were provided, along with exact 95% confidence intervals (CIs). A Wilcoxon rank-sum test was employed to compare percent improvement in PASI scores.

Patients who received ≥1 guselkumab injection and had ≥1 valid PK blood sample drawn were included in PK analyses. Safety data were evaluated for patients who self-administered ≥1 study agent injection and analyzed according to actual treatment received. Adverse events were coded using the Medical Dictionary for Regulatory Activities (Version 20.0), and incidences were summarized by system organ class. National Cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE version 20.0) grades were employed to summarize and evaluate select clinical laboratory parameters. All safety data were summarized using descriptive statistics.

Results

**Patient disposition and baseline characteristics**

This study was conducted from 01 March 2017 to 07 February 2018 at 13 sites in three countries (United States = 7, Canada = 3, Poland = 3). Among 85 patients screened, 78 were randomized to self-inject guselkumab 100 mg (N = 62) or placebo (N = 16). Thirteen of the 16 placebo patients crossed over to self-inject guselkumab at Week 16, and 66/78 (85%) randomized patients completed study participation (Figure 2).

The overall study population presented with longstanding (mean duration of psoriasis: 18.7 years), extensive (mean BSA involved: 19.8%), and moderate-to-severe (mean PASI score: 18.0, IGA score of 3 in 84.6% of patients, IGA score of 4 in 15.4% of patients) psoriasis at study initiation. A substantial proportion of patients (76.9%) had previously received one or more of the following psoriasis treatments: phototherapy (51.3%), non-biologic systemic therapy (46.2%), or biologic therapy (57.7%); 23.1% of patients were naïve to all prior non-biologic systemic and biologic therapies. Baseline patient and disease characteristics were generally comparable between randomized treatment groups (Table 1).

**Efficacy**

Guselkumab treatment afforded significant improvement in psoriasis as measured by PASI and IGA responses at Week 16 (co-primary endpoints), with significantly greater proportions of guselkumab-treated than placebo-treated patients achieving IGA 0/1 (80.6% versus 0%; p < 0.001) and PASI90 (75.8% versus 0%; p < 0.001) responses (Figure 3).

Consistently, significantly greater proportions of guselkumab-than placebo-treated patients achieved the major secondary endpoints of IGA 0 (56.5% versus 0%; p < 0.001) and PASI100 (50.0% versus 0%; p < 0.001) responses at Week 16 (Figure 3) and additional secondary endpoints of IGA ≤ 2 (93.5% versus 0%; p < 0.001), PASI50 (93.5% versus 0%; p < 0.001), and PASI75 (88.7% versus 0%; p < 0.001) responses at Week 16 (Table 2). The percent improvement from baseline in PASI score at Week 16 also was significantly higher among guselkumab-than placebo-treated patients (median: 100% versus 3%; p < 0.001).

Onset of response as measured by IGA and PASI was rapid, with numerical differences between the guselkumab and placebo groups observed as early as Week 4; continued improvement was noted through Week 20. Placebo-treated patients who crossed...
over to guselkumab at Week 16 also demonstrated rapid improvement following the start of active therapy (Figure 3). IGA 0/1 and PASI90 response rates exceeded 80% at Week 32, the last on-treatment efficacy assessment after the final guselkumab administration at Week 28 (Figure 3).

Usability and acceptability

All patients at all visits (Weeks 0, 4, 12, 16, 20, 24, 28, and 32) successfully completed self-injections with one device on the first attempt, except one patient who did not remove the device cap prior to the initial injection attempt (which damaged the internal components of the device and resulted in an inability to deliver the dose; reported as a product quality complaint).

Through Week 28, SIAQ postdose scores were favorable (overall mean scores ranged from 7.63 to 9.84) and comparable between the guselkumab and placebo groups at all time points across all six domains (feeling about injections, self-image, self-confidence, pain and skin reactions during or after the injection, ease of use of the self-injection device, and satisfaction with self-injection) (Figure S1). Specific to pain and skin reactions (burning sensation, cold sensation, itching, redness, swelling, bruising, or hardening at the injection site) during and/or after the injection, the overall postdose domain scores were very high at Week 0 (mean: 9.83) through Week 28 (mean: 9.79) indicating patients were largely ‘not at all’ bothered by injection-site pain or skin reactions. Further, regardless of study agent, most patients rated the One-Press device as easy/very easy to use from Weeks 0–28 (87%–100%) and were satisfied/very satisfied with their One-Press experience during the same timeframe (81%–100%) (Figure S2).

According to results for the patient-controlled injection device questionnaire, the majority of patients overall ‘strongly agreed’ or ‘agreed’ that they liked being able to inject the medication at a speed that was comfortable for them (97.3% of patients), that the design of the handle made the device easy to use (97.3%), and that they could easily tell when the injection was finished (94.7%).

PK and immunogenicity

Steady-state serum guselkumab concentrations were achieved by Week 20 (mean = 1.07 µg/mL; median = 0.90 µg/mL). Serum guselkumab concentrations exceeded the LLQ through Week 40 (i.e. 4 weeks beyond the recommended q8w dosing interval).
Among the 75 guselkumab-treated patients with appropriate samples, 11 (14.7%) developed antibodies to guselkumab through Week 40. Antibody titers were low (ranging from 1:10 to 1:320), and all antibodies were non-neutralizing.

Safety

Through Week 16 (placebo-controlled period), AEs were reported by similar proportions of guselkumab- and placebo-treated patients (62.9% and 68.8%, respectively). The most common AEs were injection-site pain (40.3% and 43.8%, respectively) and injection-site coldness (22.6% and 18.8%, respectively). Also through Week 16, discontinuation rates due to AEs were 1.6% for guselkumab- and 6.3% for placebo-treated patients; two two guselkumab-treated patients had serious adverse events (SAEs; 1 chest discomfort and 1 atypical chest pain) (Table 3). Through Week 40, AE reporting patterns among guselkumab-treated patients were consistent (Table 3).
Infections occurred in 19.4% of guselkumab- and 6.3% of placebo-treated patients through Week 16 and 33.3% of guselkumab-treated patients through Week 40. The proportions of patients with infections requiring oral or parenteral antimicrobial treatment were comparable between treatment groups (9.7% of guselkumab-treated patients and 6.3% of placebo-treated patients) at Week 16. One serious infection (diverticulitis) occurred in a guselkumab-treated patient (Table 3). No cases of active TB, malignancies, investigator-reported MACE, anaphylaxis and/or serum sickness-like reactions to study agent, or suicidal ideation/behavior were reported through Week 40. Rates of abnormal laboratory results were low, and no differences between groups were noted.

Regardless of whether guselkumab or placebo was injected, approximately 30% of patients reported ISRs at Weeks 0, 4, 12, and 28 (visits at which the SIAQ was administered) and all ISRs at these visits had corresponding positive SIAQ results reported by the patient in the SIAQ domain of ‘Pain and skin reactions during or after the injection’ (i.e. none of the ISRs reported at these visits were identified based on investigator assessment). Across treatment arms, only one ISR was reported (for placebo) at Week 16 (the first dosing visit at which the SIAQ was not administered), and no patients in either group reported an ISR at Week 20 (the second visit with no SIAQ assessment). The majority of ISRs were mild; none were severe. Most symptoms related to an ISR, in which duration was reported, resolved immediately or within 5 min after injection.

Discussion

This study (ORION) evaluated the efficacy, safety, and PK of guselkumab treatment when administered using the novel One-Press device in patients with moderate-to-severe plaque-type psoriasis. At Week 16, guselkumab was superior to placebo by substantial margins based on two co-primary endpoints (IGA 0/1 and PASI90) and demonstrated comparable efficacy and safety profiles to those observed at Week 16 in VOYAGE 1 and VOYAGE 2, both of which utilized guselkumab administered by the UltraSafePlus™ prefilled syringe (10,11). Comparisons between the current and previously conducted Phase 3 guselkumab trials are justified, given consistent eligibility criteria, comparable study populations, and similar trial designs. In addition, both major secondary endpoints were met in this study, with significantly higher proportions of patients in the guselkumab group achieving IGA 0 and PASI100 responses at Week 16 compared with the placebo group. Responses were generally maintained through Week 32.

This study collected patient-reported assessments of their perceptions about injections and experience with the One-Press device. Through Week 28, SIAQ postdose scores were favorable and were stable or improved over time, at all time points, and across the six domains assessed. Specifically, predose mean scores for feelings about, self-confidence with, and satisfaction with self-injection at Week 0 ranged from 6.59 to 8.23 before the first injection and from 8.48 to 9.29 after the last injection at Week 28, suggesting that patients had favorable or very favorable impressions of the device. Responses derived from the questionnaire specific to the patient-controlled injection device also indicated a high level of satisfaction how well the One-Press device functioned.

Rates and types of AEs, SAEs and laboratory abnormalities were generally comparable between the guselkumab and placebo groups through Week 16. No deaths, opportunistic infections, cases of active TB, malignancies, investigator-reported MACE, anaphylactic or serum sickness-like reactions, or suicidal ideation or behavior were reported through Week 40. Although more guselkumab- than placebo-treated patients reported infections through
Week 16 (primarily due to upper respiratory infections), the proportions of patients reporting infections requiring treatment were comparable between treatment groups. The difference in rates of infections likely may be attributed to the relatively small study size (especially the limited number of patients in the placebo group [N=16]), and the variability in rates of events that may be seen based on small numbers. Additionally, in the two, much larger, pivotal Phase 3 studies for guselkumab, rates of infections, infections requiring treatment, and serious infections were comparable between the guselkumab and placebo groups (10,11). Although the relatively small number of patients enrolled (the major study limitation) impacts the ability to assess safety, the data from this study were consistent with the safety profile of guselkumab established to date based on a much more extensive dataset. The guselkumab safety profile remained consistent through Week 28, and no new safety concerns were evident (10,11,16).

The proportions of patients who reported ISRs through Week 16 were comparable between the guselkumab and placebo groups. The majority of ISRs in this study were considered mild, and no ISR was reported as severe. The overall ISR rate seen in this study (≥30%) was higher than that observed in VOYAGE 1 and VOYAGE 2 (≥1 to 2%) (10,11,16); however, this finding reflects that this was the first study in the guselkumab psoriasis program to specifically solicit ISR data using a validated patient-reported outcome instrument (SIAQ) in addition to the standard reporting methodology. Only one (1.4%) ISR was reported for placebo and guselkumab injections combined at Week 16, and no ISRs were reported at Week 20, time points at which SIAQ data were not collected. These data are comparable and consistent with the occurrence of ISR AEs in VOYAGE 1 and VOYAGE 2 (10,11). Further, the very high SIAQ postdose domain score (mean = 9.79) for ‘Pain and skin reactions during or after the injection’ indicated that patients were virtually ‘not at all’ bothered by the reactions they were reporting (a score of 10 equals ‘not at all’ bothered). Therefore, it appears that incorporating the SIAQ responses into ISR determination may have inflated the incidence observed, by essentially soliciting reports of injection-site sensations rather than what is typically considered ISRs.

Among patients randomized to and treated with guselkumab, mean/median trough serum guselkumab concentrations were similar at Week 20 and Week 28. This indicates that the serum guselkumab concentration achieved steady state by Week 20 with the One-Press device (i.e. 20 weeks after the first SC administration of guselkumab at Week 0), which is consistent with data from the pivotal Phase 3 guselkumab psoriasis studies using the UltraSafe Plus prefilled syringe (10,11). The incidence of antibodies to guselkumab detected using a sensitive and drug-tolerant ECLIA method was 14.7% through Week 40. Although higher than the rates observed in the pivotal Phase 3 studies (10,11), the precision of the point estimates for this study are relatively low given the small number of guselkumab-treated patients. None of the antibodies to guselkumab that developed were neutralizing, and most patients who tested positive for antibodies to guselkumab had low titers. Importantly, all patients positive for antibodies to guselkumab achieved IGA 0/1 and PASI90 responses at Week 40 (i.e. 12 weeks after the last dose at Week 28), demonstrating that the presence of antibodies did not influence clinical response.

In conclusion, guselkumab administered using the One-Press device is highly efficacious in patients with moderate-to-severe psoriasis. Guselkumab was well-tolerated, and no new or additional safety concerns were identified. Results from this study through Week 40 were generally consistent with the established efficacy, safety, and PK profiles of guselkumab administered using the UltraSafe Plus device in two large Phase 3 pivotal psoriasis studies (10,11). Based on the aggregate findings from the ORION study, guselkumab can be effectively self-administered by patients using the convenient, easy-to-use, One-Press device.

**Ethical approval**

The study was conducted in compliance with the principles of the Declaration of Helsinki and Good Clinical Practices. The ORION study protocol was approved by governing ethical bodies at each participating site. All patients provided written informed consent prior to the conduct of any study-related procedures.

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**ORCID**

Laura K. Ferris [1](http://orcid.org/0000-0003-3000-2165)
Elyssa Ott [1](http://orcid.org/0000-0002-4090-8959)
Jingzhi Jiang [1](http://orcid.org/0000-0002-4662-3268)
H. Chih-Ho Hong [1](http://orcid.org/0000-0001-9963-8319)
Shu Li [1](http://orcid.org/0000-0003-3164-1348)
Chenglong Han [1](http://orcid.org/0000-0001-7175-7834)
Wojciech Baran [1](http://orcid.org/0000-0003-2732-3494)

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