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Secukinumab improves patient-reported psoriasis symptoms of itching, pain, and scaling: results of two phase 3, randomized, placebo-controlled clinical trials

Original Article/Report

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Running head: Secukinumab improves patient-reported psoriasis symptoms

ABSTRACT

Background: Secukinumab is a human interleukin-17A antagonist indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. The objective of this analysis was to measure treatment response on psoriasis-related itching, pain, and scaling via the Psoriasis Symptom Diary (PSD).

Methods: ERASURE (N = 738) and FIXTURE (N = 1,306) were double-blind, multicenter phase 3 studies in adults randomized to secukinumab (300 mg, 150 mg, n = 1,144) or placebo (n = 574) (administered at weeks 0, 1, 2, 3, and 4, followed by dosing every 4 weeks) or a biologic active control (FIXTURE only). Patient-reported itching, pain, and scaling were assessed during the first 12 weeks of treatment using the PSD.

The results reported here are limited to subjects in the secukinumab and placebo treatment groups who completed the PSD. The proportions of subjects achieving prespecified responses (improvement/reduction of at least 2.2 points for itching, 2.2 points for pain, or 2.3 points for scaling) were compared for secukinumab versus placebo.

Results: Overall, 39% of subjects completed the PSD at baseline and week 12 (N = 453 secukinumab; 225 placebo). Subjects treated with secukinumab achieved significantly greater improvements in itching, pain, and scaling at week 12 versus placebo (all $P < 0.0001$) and had significantly greater proportions of itching, pain, and scaling responders at week 12 versus placebo (all $P < 0.05$).

Conclusion: Secukinumab significantly improves patient-reported itching, pain, and scaling in adults with moderate to severe psoriasis compared with placebo.

Key words: psoriasis, secukinumab, patient reported outcome, itching, pain, scaling, Psoriasis Symptom Diary

INTRODUCTION

Psoriasis is an immune-mediated disease characterized by red, scaly patches, papules, and plaques covered by silvery scales, most often on the lower back, scalp, elbows, and knees.¹ Patients with psoriasis exhibit a broad spectrum of symptoms, including itching, pain, and scaling.²

Topical therapy is common but rarely sufficient in patients with moderate to severe psoriasis. Usually, such patients require treatment such as systemic, biologic, or phototherapy.³ Secukinumab is a human interleukin-17A (IL-17A) antagonist indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.⁴ Phase 3 studies have shown secukinumab 300 mg and 150 mg to be efficacious for improving skin clearance and to have a good safety profile.⁵

Treatment success was evaluated in these phase 3 studies using two clinical assessments as coprimary endpoints: the proportion of subjects who achieved a reduction in the Psoriasis

Area and Severity Index (PASI) of at least 75% from baseline to week 12 and the proportion who achieved clear or almost clear response on the Investigator's Global Assessment modified 2011 (IGA) at week 12. The PASI is a composite index that incorporates both the percentage of body surface area affected by psoriasis and the nature and severity of psoriatic changes within the affected regions. The IGA is a 5-category scale indicating the physician's overall assessment of psoriasis severity, evaluating area of involvement, induration, erythema, and scaling. The latter three parameters are evaluated with categories of "0 = clear," "1 = almost clear," "2 = mild," "3 = moderate," or "4 = severe" ("clear" or "almost clear" have no signs of psoriasis or normal to pink coloration of lesions, no thickening of the plaque, and none to minimal focal scaling).⁶ Other evaluated outcomes included the proportion of subjects who achieved a reduction in PASI score of at least 90% (PASI 90) from baseline at week 12, and maintenance of efficacy to week 52. Additionally, the Psoriasis Symptom Diary (PSD),^{2,7} a patient-reported assessment tool, was included to provide information on patients' perceptions of psoriasis signs and symptoms, which is essential to understanding the effects of psoriasis and its treatment on patients' lives.

The importance of incorporating the patient perspective has been acknowledged by regulatory agencies (e.g., Food and Drug Administration⁸ and European Medicines Agency⁹) and the Medical Advisory Board of the National Psoriasis Foundation.¹⁰ The PSD^{2,7} was developed as a psoriasis-specific measure in accordance with the United States Food and Drug Administration's (FDA's) guidance for patient-reported outcome (PRO) measures.⁸

Qualitative interviews among patients with moderate to severe plaque psoriasis conducted during development of the PSD identified three key psoriasis-related symptoms—itching, pain, and scaling. During the patient interviews, all patients reported experiencing psoriasis symptoms of itching and pain (100% mentioned), and most reported experiencing scaling (72% mentioned). All patients found these symptoms to be highly bothersome.² These results supported conclusions from a literature review and expert interviews and led to selection of itching, pain, and scaling, as measured by the PSD, as secondary endpoints for the ERASURE and FIXTURE secukinumab trials.⁵

The primary objective of the current analysis was to confirm the treatment response of secukinumab versus placebo in the treatment of moderate to severe plaque psoriasis based on patient-reported changes in itching, pain, and scaling. Results of key clinical evaluations of PASI and IGA are provided in a supplemental appendix (Appendix Table 1).

MATERIALS AND METHODS

Study Design

The current analysis used pooled data from two randomized, double-blind, double-dummy, placebo-controlled, multicenter phase 3 trials (ERASURE and FIXTURE) designed to assess the efficacy and safety of subcutaneous secukinumab in subjects with moderate to severe plaque psoriasis.⁵ Eligible subjects were randomized into treatment arms stratified by geographical region and by body weight (< 90 kg or ≥ 90 kg). Fig. 1 provides an overview of the study designs. Both trials had four periods: screening (1 to 4 weeks), induction (12 weeks), maintenance (40 weeks), and follow-up (8 weeks). Subjects in ERASURE were randomized 1:1:1 to receive subcutaneous secukinumab 300 mg, secukinumab 150 mg, or placebo at weeks 0, 1, 2, 3, and 4, followed by dosing every 4 weeks. Subjects in FIXTURE were randomized 1:1:1:1 to receive secukinumab 300 mg, secukinumab 150 mg, a biologic active control, or placebo.

FIGURE 1 HERE

The clinical trials were designed, implemented, and reported in accordance with the International Conference on Harmonisation's Harmonised Tripartite Guidelines for Good Clinical Practice, with applicable local regulations (including European Directive 2001/20/EC, United States Code of Federal Regulations Title 21, and Japanese Ministry of Health, Labor, and Welfare), and with the ethical principles in the Declaration of Helsinki. Eligible subjects were included in the study only after providing written (and witnessed, where required by law or regulation) institutional review board/independent ethics committee-approved informed consent or, if any subject was incapable of doing so, after such consent was provided by a legally acceptable representative of the subject. Langley and colleagues⁵ provide additional study details and clinical outcomes.

Sample

A total of 2,044 men and women (ERASURE [N = 738] and FIXTURE [N = 1,306]) with moderate to severe plaque psoriasis were randomized in these phase 3 trials of secukinumab. Key inclusion criteria were: (1) a diagnosis of chronic plaque psoriasis for at least 6 months before study entry; (2) a PASI score of 12 or greater, an IGA score⁶ of 3 (moderate) or 4 (severe), and at least 10% body surface area involvement with psoriasis; and (3) candidacy for systemic therapy (chronic plaque psoriasis inadequately controlled by topical treatment and/or phototherapy and/or previous systemic therapy).

Key exclusion criteria included other forms of psoriasis, drug-induced psoriasis, ongoing use of prohibited psoriasis treatments, previous exposure to secukinumab or other interleukin-17 pathway inhibitors, pregnant or nursing women, active inflammatory disease, active systemic infections, significant medical problems, past medical history record of human immunodeficiency virus infection, and hepatitis B or hepatitis C. In FIXTURE, exclusion included previous receipt of a biologic active control.

Across the 30 countries participating in the trials, 31 language versions of the PSD were provided for data collection. Although investigators were encouraged to administer and subjects were encouraged to complete the PSD when available, its use was not mandatory in the trials. Translations were not available for two countries. In addition, the electronic device used to administer the PSD was not available for two countries due to customs delays. The present analysis was limited to subjects in the secukinumab and placebo treatment groups who completed the PSD at baseline and week 12.

Patient-Reported Outcomes

The PSD was developed by Novartis to capture the daily signs and symptoms of psoriasis reported by the patient, based on 16 items evaluating psoriasis-related characteristics that patients found important (Appendix Table 2). Seven items evaluate psoriasis-related signs and symptoms including itching, pain, and scaling. The remaining items assess patient-reported bother associated with these signs and symptoms and daily impacts. The results reported here focus only on three psoriasis-related signs and symptoms—itching, pain, and scaling—selected as the key symptoms based on patient input during the development of the

PSD.² Novartis interacted with the FDA and the European Medicines Agency (EMA) regarding the development and use of the PSD and followed the development and validation principles in the FDA PRO guidance.^{7,11}

Subjects were scheduled to complete the PSD electronically once each evening from screening through week 12. Each item was rated on a scale of 0 through 10, with 0 indicating no effect and higher scores indicating worse effects of psoriasis. A weekly average was computed for each item as the sum of the scored item over the course of the study week divided by the number of days on which the item was completed (4 completed days were required to derive a weekly score; 1 to 3 missed days, consecutive or nonconsecutive, were allowed per week). If fewer than 4 completed days were in a study week, the item scores were set to missing.

Analytic Methods

Analyses of the three PSD items—itching, pain, and scaling—were conducted using the 12-week induction period for subjects with a baseline and week 12 PSD assessment. A two-sided alpha level of 0.05 was used unless otherwise specified.

For the PSD endpoints of itching, pain, and scaling, the change from baseline to week 12 was analyzed in separate analysis of covariance (ANCOVA) models with covariates for treatment, geographical region, body weight stratum, and baseline PSD itching, pain, and scaling values. Differences between treatment groups were determined via least square means and *t* tests using the pooled error term from the linear model. Improvement was indicated by negative change scores.

The proportion of responders for each of the three symptoms at week 12 was compared by treatment using a Cochran-Mantel-Haenszel test stratified by geographic region and body weight. For this analysis, prespecified responder thresholds identified in the PSD psychometric evaluation using phase 2 data were applied: subjects were classified as responders if they achieved improvement/reduction of at least 2.2 points for itching, 2.2 points for pain, or 2.3 points for scaling from baseline.⁷

RESULTS

Subject Characteristics

Of the 1,718 subjects randomized to secukinumab and placebo, 39% (678/1,718) completed the PSD at baseline and week 12. Baseline demographics and disease characteristics were similar across treatment groups (Table 1) and similar to those previously reported in the overall trial population.⁵ Subjects were roughly equally distributed across the treatment arms. The mean age of subjects ranged from 43.0 years (secukinumab 150 mg) to 45.7 years (secukinumab 300 mg). Mean PASI scores at baseline were 21.9, 21.8, and 21.6 for the secukinumab 300-mg, secukinumab 150-mg, and placebo groups, respectively. Based on the IGA, the majority of subjects in each group had moderate disease (i.e., score of 3 based on a 0-4 scale). Baseline scores for itching, pain, and scaling were similar across groups.

TABLE 1 HERE

Itching, Pain, and Scaling Treatment Response

The ANCOVA for change from baseline to week 12 for itching, pain, and scaling showed that subjects treated with secukinumab 300 mg or 150 mg reported significantly greater improvement (defined as negative mean change scores from baseline to week 12) versus placebo for all three symptoms (least square mean changes of −5.14 for secukinumab 300 mg, −4.9 for secukinumab 150 mg, and −0.4 for placebo for itching; −4.52 for secukinumab 300 mg, −4.02 for secukinumab 150 mg, and −0.16 for placebo for pain; −5.15 for secukinumab 300 mg, −4.83 for secukinumab 150 mg, and −0.28 for placebo for scaling; $P < 0.0001$ for each comparison) (Fig. 2).

FIGURE 2 HERE

Itching, Pain, and Scaling Week 12 Response Rates

Fig. 3 presents the proportion of subjects classified as responders at week 12 for each treatment group. Response rates for itching (achieving the predetermined improvement/reduction of at least 2.2 points), pain (at least 2.2 points), and scaling (at least 2.3 points) were significantly higher in the secukinumab groups than the placebo group at

week 12. At week 12, itching response was achieved in 83.0% subjects on secukinumab 300 mg and 78.2% subjects on secukinumab 150 mg versus 16.9% of the placebo subjects. Similarly, at week 12, pain response was achieved in 72.8% subjects on secukinumab 300 mg and 65.5% subjects on secukinumab 150 mg versus 15.6% of the placebo subjects. At week 12, scaling response was achieved in 83.0% subjects on secukinumab 300 mg and 78.2% subjects on secukinumab 150 mg versus 13.8% of the placebo subjects.

FIGURE 3 HERE

DISCUSSION

The PSD was designed to focus on the signs, symptoms, and impact of moderate to severe plaque psoriasis.^{2,7} The present analysis confirmed the treatment response of secukinumab versus placebo on three key patient-reported signs and symptoms (itching, pain, and scaling) as assessed by the PSD. At week 12, improvements in itching, pain, and scaling reported by subjects treated with secukinumab were significantly higher than for subjects treated with placebo.

Although the PSD was completed by only approximately 39% of subjects, their clinical and demographic characteristics were similar to those of the overall trial population (previously reported⁵), suggesting that results may be generalized to the full study population. Although the PSD sample size was reduced, it was adequate to determine meaningful differences between secukinumab and placebo.

Most psoriasis clinical trials rely on visible signs evaluated by a physician to assess treatment efficacy. The PASI, the most widely used evaluation of psoriasis severity in clinical trials, provides a composite score of scaling, erythema, and plaque thickness and body surface area involved, as measured by the investigator. Tools such as the PSD provide disease-specific patient ratings of signs and symptoms.^{2,7}

Patients cite itching and pain as the most troublesome psoriasis symptoms.² Therefore, an effective psoriasis therapy that clears plaque thickness, erythema, and scaling should also improve the patient-reported symptoms of itching and pain.

CONCLUSION

Secukinumab, a human interleukin-17A antagonist, significantly improves psoriasis-related patient-reported itching, pain, and scaling compared with placebo.

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TABLE

Table 1. Subject Demographic and Clinical Characteristics at Baseline for Those Completing the PSD

Demographics and Characteristics	Secukinumab	Secukinumab	Placebo
	300 mg (n = 224)	150 mg (n = 229)	
Male, n (%)	140 (62.5%)	151 (65.9%)	160 (71.1%)
Age, mean (SD), n	43.0 (13.1), 224	45.7 (12.9), 229	43.1 (11.7), 225
Body weight, mean, n (%)	90.3 (23.1)	89.3(22.2)	89.5 (23.3)
PASI			

Demographics and Characteristics	Secukinumab	Secukinumab	Placebo
	300 mg (n = 224)	150 mg (n = 229)	
Mean (SD), n	21.9 (9.0), 224	21.8 (9.0), 229	21.6 (8.7), 224
Range	12.0-64.2	12.0-69.6	10.6-50.2
IGA			
Moderate (level = 3), n (%)	141 (63.0%)	152 (66.4%)	138 (61.3%)
Severe (level = 4), n (%)	83 (37.1%)	77 (33.6%)	87 (38.7%)
PSD			
Itching mean (SD), n	6.4 (2.4), 224	6.5 (2.4), 229	6.1 (2.5), 225
Pain mean (SD), n	5.5 (3.0), 224	5.3 (3.1), 229	5.0 (3.0), 225
Scaling mean (SD), n	6.4 (2.6), 224	6.5 (2.4), 229	6.2 (2.4), 225

IGA = Investigator's Global Assessment modified 2011; PASI = Psoriasis Area and Severity Index; PSD = Psoriasis Symptom Diary (0-10 numerical symptom rating scale via daily diary); SD = standard deviation.

TABLE LEGEND

Table 1. Subject Demographic and Clinical Characteristics at Baseline for Those Completing the PSD

IGA = Investigator's Global Assessment modified 2011; PASI = Psoriasis Area and Severity Index; PSD = Psoriasis Symptom Diary (0-10 numerical symptom rating scale via daily diary); SD = standard deviation.

FIGURE LEGENDS

Figure 1. ERASURE and FIXTURE Study Designs

q4wk = every 4 weeks; R = randomization; wk = week.

^a Treatment or placebo at baseline and weeks 1, 2, 3, 4, and 8; short arrows indicate time points at which doses were given during induction period.

^b Maintenance treatment started at week 12 and continued q4wk until week 48.

^c Treatment at weeks 12, 13, 14, and 15.

^d Treatment q4wk from week 16 until week 48.

^e Placebo at weeks 12, 13, 14, and 15, then q4wk from week 16 until week 48.

Figure 2. Mean Change From Baseline to Week 12 in Psoriasis Symptom Diary Itching, Pain, and Scaling by Treatment Group at Week 12 (LS Means)

LS = least square; PSD = Psoriasis Symptom Diary.

$P < 0.0001$ vs. placebo for secukinumab 150 mg and 300 mg for itching, pain, and scaling.

Treatment differences in the psoriasis-related symptoms were examined using an ANCOVA with geographical region, body weight stratum, and baseline value as covariates.

Figure 3. Psoriasis Symptom Diary Itching, Pain, Scaling Responder Rates at Week 12

PSD = Psoriasis Symptom Diary.

Note: Achieving at least the predetermined improvement/reduction of 2.2 points for itching, 2.2 points for pain, or 2.3 points for scaling from baseline (definition of responder).

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