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BRIEF REPORT

Incidence of Uveitis in Secukinumab-treated Patients With Ankylosing Spondylitis: Pooled Data Analysis From Three Phase 3 Studies

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Objective. The objective of this study was to report the incidence of uveitis in secukinumab-treated patients with ankylosing spondylitis (AS) in a pooled analysis of three phase 3 trials (MEASURE 1-3 [ClinicalTrials.gov identifiers NCT01358175, NCT01649375, NCT02008916]).

Methods. Analysis included pooled patient-level data from all patients (N = 794) who received any dose (one or more) of secukinumab up to the last patient attending the week 156 study visit in MEASURE 1 and up to the week 156 visit in MEASURE 2 and the week 104 visit in MEASURE 3 for each patient. Postmarketing data were from the periodic safety update report. Incidence of uveitis is reported as the exposure-adjusted incidence rate (EAIR) per 100 patient-years of secukinumab exposure.

Results. Overall, 135 (17%) patients reported preexisting (but not active or ongoing) uveitis at baseline, and 589 (74.2%) patients were HLA antigen B27 positive. The EAIR for uveitis was 1.4 per 100 patient-years over the entire treatment period. Among all cases of uveitis (n = 26), 14 (54%) were flares. The exposure-adjusted reporting rate of uveitis in the postmarketing data (which included patients across the three approved indications of psoriasis, psoriatic arthritis, and AS) was 0.03 per 100 patient-years based on cumulative secukinumab exposure of 96 054 patient-years.

Conclusion. The incidence rate of uveitis in secukinumab-treated patients with active AS does not suggest an increased risk with secukinumab treatment.

INTRODUCTION

Uveitis is immune-mediated intraocular inflammation of the uvea, which comprises the iris, ciliary body, and choroid. Uveitis can be anterior, intermediate, posterior, or pan uveitis and can occur in association with or without retinal vasculitis (1). The estimated prevalence of uveitis ranges from 100 to 150 per 100 000 patient-years, and it has an incidence of 20 to 50 per 100 000 patient- years in Europe and the United States (2).

Uveitis, specifically anterior uveitis, is considered as the most common extraarticular manifestation in spondyloarthritis (SpA). It is strongly associated with HLA antigen B27 (HLA-B27) positivity (3). The lifetime prevalence of anterior uveitis in patients with SpA has been reported as 30% or more and is characterized by the

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SIGNIFICANCE & INNOVATION

- Uveitis is considered a common extraarticular manifestation in spondyloarthritis (SpA), with a lifetime prevalence of 30% or more in patients with SpA.
- This is the first pooled analysis reporting the incidence of uveitis undertaken in a large population of patients with ankylosing spondylitis (AS) treated with secukinumab from three phase 3 clinical trials.
- The exposure-adjusted incidence rate of uveitis (new-onset cases and flares) in secukinumab-treated patients with active AS was 1.4 per 100 patient-years in pooled phase 3 MEASURE trials over 4 years of treatment.
- Overall, the currently analyzed data did not suggest an increased risk of uveitis in these secukinumab-exposed cohorts.

possibility of recurrence (flare) (2,4). The presence of HLA-B27 and disease duration are well-recognized risk factors for uveitis in patients with ankylosing spondylitis (AS). Although it may be subject to interstudy variability, the prevalence of uveitis was 20% at 5 years after diagnosis of AS, which increased to 39% at 20 years after diagnosis, indicating that prevalence of uveitis should also be analyzed considering disease duration (5).

Interleukin 17A (IL-17A) is recognized as one of the principal pro-inflammatory cytokines in immune-mediated inflammatory diseases, and secukinumab, a human monoclonal antibody that directly inhibits IL-17A, was explored for efficacy in the treatment of noninfectious uveitis in four clinical trials. The primary efficacy end points of three studies in which secukinumab was given by the subcutaneous route were not met, although the secondary efficacy data from these studies did suggest a beneficial effect of secukinumab in reducing the use of concomitant immunosuppressive medication. One study (ClinicalTrials.gov identifier NCT00685399) showed that intravenous secukinumab was effective and well tolerated in patients with noninfectious uveitis who required systemic corticosteroid-sparing immunosuppressive therapy (6). Secukinumab has demonstrated rapid and sustained efficacy and safety in patients with AS across phase 3 studies (7). There is interest among rheumatologists to study the incidence of uveitis with secukinumab treatment. We report post hoc pooled analyses of the incidence of uveitis in secukinumab-treated patients with AS from three long-term phase 3 trials (MEASURE 1-3).

PATIENTS AND METHODS

Study design and patients. The design and inclusion and exclusion criteria of the MEASURE studies have been reported in detail (7). In MEASURE 1 (ClinicalTrials.gov identifier NCT01358175), 371 patients were randomly assigned to receive 10 mg/kg of intravenous (IV) secukinumab at baseline and at weeks 2 and 4, followed by 150 or 75 mg of subcutaneous (SC) secukinumab or a placebo every 4 weeks starting at week 8. In MEASURE 2 (ClinicalTrials.gov identifier NCT01649375), 219 patients were randomly assigned to receive SC secukinumab (150 or 75 mg) or a placebo at baseline and at weeks 1, 2, and 3 and every 4 weeks starting at week 4. In MEASURE 3 (ClinicalTrials.gov identifier NCT02008916), 226 patients were randomly assigned to receive IV 10 mg/kg of secukinumab at baseline and at weeks 2 and 4, followed by 300 or 150 mg of SC secukinumab every 4 weeks or a matched placebo. Placebo patients were reassigned randomly to receive 150 or 75 mg of SC secukinumab every 4 weeks at week 16 or 24 based on clinical response in MEASURE 1. In MEASURE 2 and MEASURE 3, all placebo patients were reassigned randomly to receive 300 mg (MEASURE 3 only) or 150 or 75 mg (MEASURE 2 only) of SC secukinumab every 4 weeks at week 16, irrespective of clinical response.

Relevant medical history of extraaxial involvement (uveitis, psoriasis, inflammatory bowel disease, dactylitis, enthesitis, and peripheral arthritis) were collected for all patients from a prespecified checklist completed by the investigator. Although patients with uveitis were not specifically excluded, patients with active or ongoing inflammatory diseases other than AS that might confound the evaluation of the benefit of secukinumab therapy were excluded from the study.

Postmarketing surveillance data for secukinumab were derived from periodic safety update reports combined across the psoriasis, psoriatic arthritis, and AS indications from December 26, 2014, to June 25, 2017, for which the clinical characteristics of uveitis were recorded as reported.

Statistical analyses. Analyses included patient-level data pooled from all patients who received one or more dose of secukinumab up to the date of the last patient attending the week 156 study visit in MEASURE 1 and up to the week 156 visit in MEASURE 2 and the week 104 visit in MEASURE 3 for each patient. Adverse events (AEs) were coded by using the Medical Dictionary for Regulatory Activities version 20.0 (http://www.meddramsso.com). Incidence of uveitis was reported as exposure-adjusted incidence rate (EAIR) per 100 patient-years of secukinumab exposure for clinical trial data and as exposure-adjusted reporting rates (EARRs) per 100 patient-years for postmarketing surveillance data. EARR was defined as the number of patients exposed to the drug and experiencing a certain event divided by the total exposure expressed in patient-treatment years.

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Ethics approval and consent to participate. All clinical studies were conducted in compliance with the Declaration of Helsinki, International Council for Harmonization Guidelines for Good Clinical Practice, and local country regulations. All patients provided written informed consent to participate in the respective studies.

Availability of data and material. The data sets generated and/or analyzed during the current study are not publicly available. Novartis is committed to sharing with qualified external researchers access to patient-level data and supporting clinical documents from eligible studies. These requests are reviewed and approved based on scientific merit. All data provided are anonymized to respect the privacy of patients who have participated in the trial, in line with applicable laws and regulations. The data may be requested from the corresponding author of the article.

RESULTS

Overall cohort. The current analysis included 794 patients across the 3 MEASURE studies and data on up to 4 years' duration of secukinumab treatment.

Baseline characteristics. In these phase 3 clinical trials, 135 (17%) patients reported preexisting (but not active or ongoing) uveitis at baseline and 589 (74%) patients were HLA-B27 positive. Among the 26 patients who reported an AE of uveitis in this cohort, 22 were HLA-B27 positive and had a mean (±SD) disease duration of 6.1 (±6.6) years at baseline (Table 1).

Uveitis incidence in the overall population. The EAIR for uveitis in AS clinical trials was 1.4 per 100 patient-years over the entire treatment period (N = 794). Among all physician-reported cases of uveitis (n = 26 [3.3%]), 14 (1.8%) were flares in patients with a history of uveitis at baseline and 12 (1.5%) were new-onset cases (Figure 1). Of the 26 patients who reported an AE of uveitis, one was severe (but did not lead to treatment discontinuation) and the rest were either mild or moderate in severity, recorded as reported by the investigator. Causal association with the study treatment was reported as likely in one mild and three moderate cases. Study treatment was withdrawn in two patients (one flare and one new onset) who reported an AE of uveitis, whereas treatment was not interrupted in the remaining 24 patients.

Uveitis incidence by HLA-B27 status. The EAIR of uveitis in HLA-B27-positive (n = 22) and HLA-B27-negative (n = 3) patients in AS clinical trials was 1.1 and 0.2 per 100 patient-years, respectively.

Uveitis incidence by previous anti–tumor necrosis factor treatment and secukinumab dose. Among all cases of uveitis (n = 26), 17 (eight flares and nine new onset) were in anti–tumor necrosis factor (TNF)-naïve patients (n = 567) and nine (six flares and three new onset) were in inadequate responders to anti-TNF (n = 227). Incidence of uveitis (flares and new onset) in long-term pooled AS clinical trials by secukinumab dose is reported in Table 2. The EAIRs were generally comparable across secukinumab-treated patients by secukinumab dose, and there was no dose-response relationship observed in terms of uveitis events.

Table 1. Baseline characteristics of patients analyzed

Characteristic	Any Secukinumab		
	Total Patients (N = 794)	Patients With Uveitis AE (n = 26)	Patients Without Uveitis AE (n = 768)
Age, mean (SD), y	42.4 (12.3)	38.2 (12.9)	42.5 (12.3)
Female sex, n (%)	265 (33.4)	7 (26.9)	258 (33.6)
Weight, mean (SD), kg	78.9 (17.2)	78.7 (15.3)	78.9 (17.3)
White, n (%)	612 (77.1)	17 (65.4)	595 (77.5)
Time since first diagnosis of AS, mean (SD), y	6.6 (7.9)	6.1 (6.6)	6.6 (8.0)
Relevant medical history or current medical condition, n (%)			
Uveitis	135 (17.0)	14 (53.8)	121 (15.8)
Hypertension	176 (22.2)	4 (15.4)	172 (22.4)
Hyperlipidemia	65 (8.2)	4 (15.4)	61 (7.9)
Diabetes mellitus	22 (2.8)	0	22 (2.9)
Crohn disease	5 (0.6)	0	5 (0.7)
Ulcerative colitis	3 (0.4)	0	3 (0.4)
Current smoker[a]	234 (29.5)	8 (30.8)	226 (29.4)
Methotrexate use at baseline	109 (13.7)	2 (7.7)	107 (13.9)
Anti-TNF IR[b]	227 (28.6)	9 (34.6)	218 (28.4)
HLA-B27	589 (74.2)	22 (84.6)	567 (73.8)

Abbreviation: AE, adverse event; AS, ankylosing spondylitis; HLA-B27, HLA antigen B27; IR, inadequate responder; TNF, tumor necrosis factor.
[a]Excludes past smokers who quit smoking any time prior to enrollment in the clinical study. [b]Included patients who did not respond to, lost their response to, were intolerant to, or had contraindications and could not be started on TNF agents.

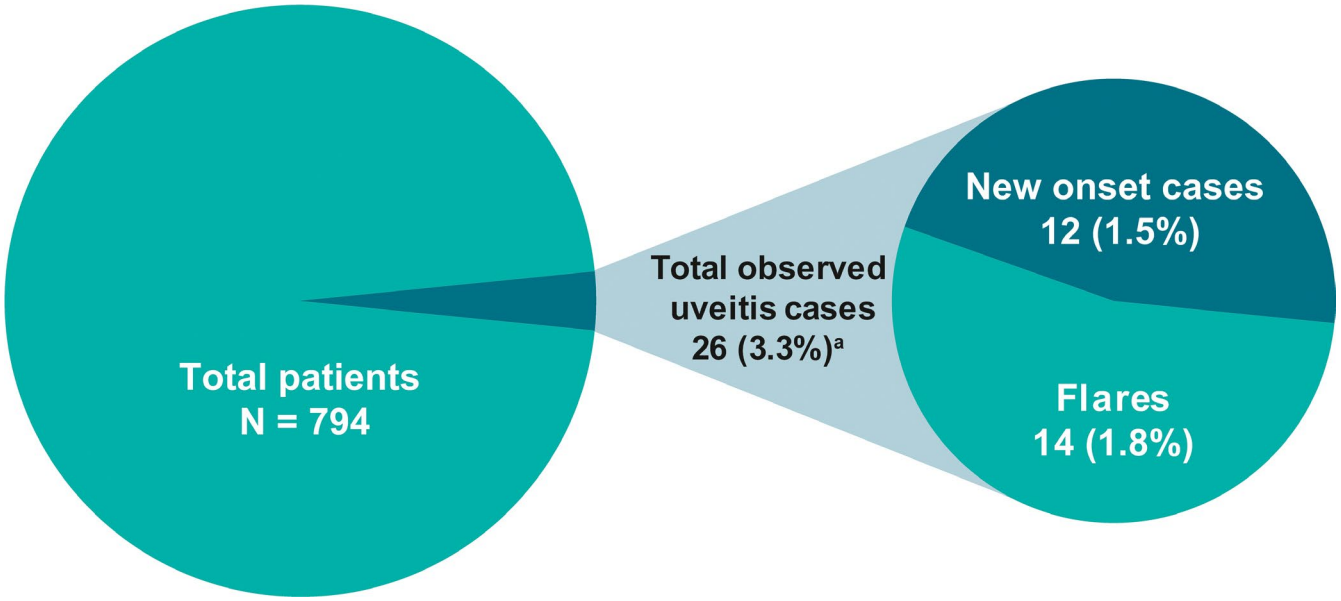

Figure 1. Uveitis in pooled secukinumab ankylosing spondylitis (AS) clinical trials. Rates reported are n (%) for the entire treatment period (N = 794) for preferred terms by using the Medical Dictionary for Regulatory Activities. [a]Includes two cases of treatment discontinuation and one case of treatment interruption.

Annual incidence rate of uveitis. The annual EAIR of uveitis in AS clinical trials ranged from 1.1 to 2.5 with decreasing sample size and a low absolute number of events reported each year (year 1: 1.1 [N = 794]; year 2: 1.9 [N = 700]; year 3: 2.2 [N = 557]; and year 4: 2.5 [N = 332]).

Uveitis reported in postmarketing data. The cumulative postmarketing exposure to secukinumab was estimated to be approximately 96 054 patient-years across the three approved indications of psoriasis, psoriatic arthritis, and AS. The cumulative number of uveitis cases reported in postmarketing data was 29, with an EARR of 0.03 case per 100 patient-years.

DISCUSSION

This is the first pooled analysis reporting the incidence of uveitis in patients with AS treated with secukinumab from three phase 3 clinical trials. Uveitis is the most common extraarticular manifestation in SpA and is associated with HLA-B27 positivity.

SpA can encompass peripheral and/or axial manifestations, and uveitis occurs with varying frequency according to the SpA subtype (approximately 33% in AS and 6%-9% in psoriatic arthritis) and the presence of HLA-B27 and with increasing duration of disease (8).

A large proportion of patients with uveitis have undiagnosed SpA, and the percentage is even higher with positive HLA-B27 status (9). The EAIR of uveitis (combined new onset and flares) reported in patients with AS treated with anti-TNF agents has been reported to be 2.6 to 3.5 per 100 patient-years (10-14). In the pooled analysis of the three phase 3 clinical trials with secukinumab reported herein, the EAIR of uveitis was 1.4 per 100 patient-years, which is reassuring given that 17% of patients had reported a prior history of uveitis and 74% of patients were HLA-B27 positive in this cohort. It is notable here that among the 26 patients who reported an AE of uveitis in this cohort, 22 (85%) were HLA-B27 positive and had a mean (±SD) disease duration of 6.1 (±6.6) years at baseline. The annual EAIR of uveitis was generally low over the 4 years of secukinumab treatment and ranged

Table 2. Uveitis incidence by secukinumab dose in pooled AS clinical trials

Type of Uveitis	Any Secukinumab, 300 mg (n = 113)	Any Secukinumab, 150 mg (n = 402)	Any Secukinumab, 7 5 mg (n = 284)	Totala (N = 794)
Flares	1	11	2	14
New onset	1	6	5	12
Total	2	17	7	26
EAIR per 100 patient-years (95% CI)	1.0 (0.1-3.7)	1.8 (1.0-2.9)	0.9 (0.4-1.9)	1.4 (0.9-2.0)

Abbreviation: AS, ankylosing spondylitis; CI, confidence interval; EAIR, exposure-adjusted incidence rate.
aRates reported for preferred terms by using the Medical Dictionary for Regulatory Activities.

from 1.1 to 2.5. These rates must, however, be viewed with caution given the decreasing sample size for each subsequent yearly interval and the relatively low absolute number of uveitis events reported each year. The rates should be followed as additional long-term exposure data are accumulated.

It is notable here that there were only two cases of uveitis that were reported as serious AEs across six phase 3 trials in the secukinumab SpA program (15) (including the one reported as a serious AE in this cohort), of which one was a complication post eye surgery (8). The EAIR of uveitis in the postmarketing data (based on the cumulative secukinumab exposure of 96 054 patient-years) was 0.03 per 100 patient-years. There were 29 cases of uveitis reported among secukinumab-treated patients, giving an incidence of less than 3 per 10 000 patient-years. However, many of these postmarketing cases were poorly documented, with at least half reported as relapsed uveitis with preexisting disease—similar to what was observed in this pooled clinical trial cohort. Almost 70% of uveitis cases were reported in patients with SpA (psoriatic arthritis and AS), with only three cases in patients with psoriasis, thus consistent with increased background rates of uveitis associated with SpA.

The strength of this report is that this analysis was undertaken in a large patient population pooled from three phase 3 clinical trials on patients with AS and complemented with postmarketing surveillance data. The use of EAIRs also enhances the robustness of the results by adjusting for disease duration. Limitations are that the data presented are from a pooled clinical trial database wherein the conduct of the clinical trials was protocol specified and not fully reflective of real-world clinical experience. The lack of a long-term placebo comparison, due to ethical considerations, limits comparison of the safety data. The incidence of uveitis reported herein was recorded as reported, generally by a rheumatologist, and not adjudicated or confirmed by an ophthalmologist. In addition, although patients with uveitis were not specifically excluded from AS trials, the exclusion of patients with active ongoing inflammatory diseases, which, in the investigator's opinion, might confound the evaluation of therapy in patients with AS, may have limited the enrollment of patients with uveitis. The postmarketing data, not separated by indication, were limited by nonstandardized documentation of reported cases and by the well-recognized subreporting of postmarketing events. Moreover, the interpretation of uveitis incidence under different biologic treatments should take into account disease duration and HLA-B27 positivity of the studied populations, two important parameters associated with uveitis flares that can substantially differ between studies.

In conclusion, in secukinumab-treated patients with active AS, the incidence rate of uveitis (new-onset cases and flares) was 1.4 patient-years in phase 3 trials over 4 years of treatment. Overall, the current data do not suggest an increased risk of uveitis in these secukinumab-exposed cohorts in the MEASURE studies.

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AUTHOR CONTRIBUTIONS

All authors were involved in the drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be published, had full access to all of the data in the study, and take responsibility for the integrity of the data and the accuracy of the data analysis.

Study conception and design. Porter, Shete.

Acquisition of data. Deodhar, Miceli-Richard, Baraliakos, Marzo-Ortega, Gladman, Blanco.

Analysis and interpretation of data. Deodhar, Miceli-Richard, Baraliakos, Marzo-Ortega, Gladman, Blanco, Das Gupta, Martin, Safi Jr, Porter, Shete, Rosenbaum.

ROLE OF THE STUDY SPONSOR

All studies were designed by the sponsor, Novartis Pharma AG, and the scientific steering committee of respective studies. Data were collected in accordance with Good Clinical Practice guidelines by the study investigators and were analysed by the sponsor. All the authors contributed to the interpretation of the data and had access to the full data sets. Statistical analyses were performed by statisticians employed by the sponsor and were reviewed by all authors. Medical writing support for this article was funded by Novartis Pharma AG in accordance with Good Publication Practice guidelines. Publication of this article was not contingent upon approval by Novartis Pharma AG.

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