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SAT0270 **LOW INCIDENCE OF BOTH NEW-ONSET AND FLARES OF UVEITIS IN SECUKINUMAB-TREATED PATIENTS WITH ANKYLOSING SPONDYLITIS: CLINICAL TRIAL AND POST-MARKETING SAFETY ANALYSIS**

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Background: Uveitis, a common extra-articular manifestation of SpA, has an estimated prevalence in patients (pts) with ankylosing spondylitis (AS) of 33.2%, which increases with disease duration and positive HLA-B27 status.¹ Uveitis occurs in 10%–50% of SpA pts.¹ The exposure-adjusted incidence rate [EAIR] of uveitis (combined new-onset and flares) reported in AS pts treated with TNF inhibitors is 2.6–3.5 per 100 patient-years (pt-yrs).^{2–5}
Objectives: To assess the incidence of uveitis in secukinumab-treated AS pts in long-term pooled clinical data from three phase 3 trials (MEASURE 1–3 [NCT01358175, NCT01649375, NCT02008916]) and from post-marketing analyses.
Methods: Analysis included pooled pt-level data from all pts in MEASURE 1 who received any dose (≥1) of secukinumab up to the last pt attending Week 156 study visit, and up to visit Week 156 in MEASURE 2 and visit Week 104 in MEASURE 3 for each patient, respectively. Post-marketing data were from the most recent periodic safety surveillance report. Incidence of uveitis is reported as EAIR per 100 pt-yrs of secukinumab exposure.
Results: In the phase 3 AS clinical trials, 135 (17%) pts reported pre-existing (but not active or ongoing) uveitis at baseline and 589 (74.2%) pts were HLA-B27 positive. The EAIR for uveitis was 1.4 per 100 pt-yrs over the entire treatment period (n=794). Among all cases of uveitis (n=26), 14 (54%) were flares in pts with a history of uveitis at baseline (Table). The EAIR of uveitis in the post-marketing data (based on cumulative secukinumab exposure of 96 054 pt-yrs) was 0.03 per 100 pt-yrs.

Abstract SAT0270 – Table 1. Safety Analysis for Uveitis with Secukinumab in AS

Data from Clinical Studies	
Number of clinical studies/pts included	3/794
Uveitis cases reported, n (%)	
Total	26 (3.3%)
New onset cases	14 (1.8%)
Treatment discontinuation	2 (0.3%)
Treatment interruption	1 (0.1%)
EAIR (95% confidence interval) per 100 pt-yrs ^a	1.4 (0.9–2.0)
Post-Marketing Data^b	
Cumulative estimated market experience (pt-treatment yrs) ^c	96 054
Cumulative number of cases reported	29
Crude incidence rate per 100 pt-yrs	0.03

^aRates are for uveitis MedDRA preferred term
^bData from the periodic safety update report (PSUR) dated 10th August 2017 – includes all indications
^cEstimated based on cumulative worldwide sales volume and the average maintenance dose

Conclusions:

In secukinumab-treated pts with active AS, a low incidence of uveitis was observed, including new-onset cases and flares, in both clinical trials and post-marketing analyses.

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SAT0271 **SECUKINUMAB, A FULLY HUMAN ANTI-INTERLEUKIN-17A MONOCLONAL ANTIBODY, EXHIBITS LOW IMMUNOGENICITY IN PATIENTS WITH PSORIATIC ARTHRITIS AND ANKYLOSING SPONDYLITIS DURING A 52-WEEK TREATMENT PERIOD**

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Background: Secukinumab (SEC), a fully human monoclonal antibody (mAb) that selectively targets IL-17A, is highly efficacious for the treatment of psoriatic arthritis (PsA) and ankylosing spondylitis (AS). mAb therapies may be associated with immunogenicity (IG) and production of anti-drug antibodies (ADAs) that may cause adverse events (AEs), and affect drug pharmacokinetics (PK) and clinical response.

Abstract SAT0271 – Table 1. Overview of pts with TE-ADA¹

PsA studies	Study	SEC dose	Prior biologics	ADA (titer)/ Neut-Ab	AE IG related	Impact on efficacy ²	PK behaviour ³
	F2306	PBO-75 mg	0	W24 (no titer)/Y	N	None	Normal
	F2312	PBO-150 mg	0	W52 (2.99)/N	N	None	Normal
	F2318	150 mg	Infliximab	W52 (2.14)/N	N	None	Normal
		150 mg	0	W24 (1.00)/N	N	None	Normal
		150 mg	0	W52 (2.59)/N	N	None	Normal
AS studies	F2305	10 mg/kg–150 mg	0	W52 (2.39)/N	N	None	Normal
		PBO-150 mg	0	W52 (10.61)/N	N	None	Normal
	F2310	PBO-75 mg	0	W52 (39.39)/N	N	None	Normal
	F2314	PBO-300 mg	0	W52 (1.02)/N	N	None	Normal
	F2320	150 mg	0	W16 (6.35)/N	N	None	Normal
				W52/ (2.96)/N			
		150 mg	0	W16 (2.70)/N	N	None	Normal
		No Load	0	W24/ (2.80)/N	N	None	Normal
		150 mg	0	W52/ (2.89)/N	N	None	Normal
		PBO–150 mg	0		N	None	Normal