FRI0272

SECUKINUMAB DEMONSTRATES A CONSISTENT SAFETY PROFILE IN PATIENTS WITH PSORIASIS, PSORIATIC ARTHRITIS AND ANKYLOSING SPONDYLITIS OVER LONG TERM: UPDATED POOLED SAFETY ANALYSES

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Background: Pooled safety data has been reported with secukinumab (SEC) in patients (pts) with Psoriatic arthritis (PsA), Ankylosing Spondylitis (AS) and Psoriasis (PsO).¹

Objectives: To report longer-term safety data of SEC treatment in PsA, AS, PsO pts up to 5 years.

Methods: The integrated clinical trial safety dataset included data pooled from 28 randomised controlled clinical trials of SEC 300 or 150 or 75mg in PsO (11 Phase 3 and 8 Phase 4 trials), PsA (5 Phase 3 trials), and AS (4 Phase 3 trials), along with post-marketing safety surveillance data with a cut-off date of 25 December 2018. Adverse events (AEs) were reported as exposure-adjusted incident rates (EAIRs) per 100 pt-years. Analyses included all pts who received ≥1 dose of SEC.

Results: A total of 12637 pts (8819, 2678 and 1140 pts with PsO, PsA and AS, with an exposure of 15063.1, 5984.6 and 3527.2 pt-years, respectively) were included. The most frequent AE was upper respiratory tract infection and EAIR per 100 pt-years for IBD, malignancies and MACE remained low. The EAIR per 100 pt-years for adverse events (AEs) of special interest are reported in Table 1. The cumulative post-marketing exposure to SEC was estimated to be ~285,811 pt-years across the approved indications. Safety data from post-marketing surveillance are reported in Table 2.

Table 1. Selected AEs of interest with SEC across pooled clinical trials

Variable	PsO	PsA	AS
	SEC N=8819	SEC N=2678	SEC N=1140
Exposure (Days), Mean (SD)	623.9 (567.7)	816.2 (580.7)	1130.1 (583.0)
Death, n (%)	15 (0.2)	13 (0.5)	10 (0.9)
Selected AE's of interest, EAIR (95% CI)			
Serious infections ¹	1.4 (1.2, 1.6)	1.8 (1.5, 2.2)	1.2 (0.9, 1.6)
Candida infections ²	2.9 (2.7, 3.2)	1.5 (1.2, 1.9)	0.7 (0.5, 1.1)
IBD ³	0.01 (0.0, 0.05)	0.03 (0.0, 0.1)	0.03 (0.0, 0.2)
Crohn's disease ³	0.1 (0.05, 0.2)	0.1 (0.04, 0.2)	0.4 (0.24, 0.7)
Ulcerative colitis ³	0.1 (0.08, 0.2)	0.1 (0.04, 0.2)	0.2 (0.1, 0.5)
MACE ⁴	0.4 (0.31, 0.5)	0.4 (0.3, 0.6)	0.7 (0.4, 1.0)
Uveitis ³	0.01 (0.0, 0.05)	0.1 (0.04, 0.2)	1.2 (0.9, 1.7)
Malignancy ⁵	0.9 (0.7, 1.0)	1.0 (0.77, 1.3)	0.5 (0.3, 0.8)

¹Rates for system organ class; ²Rates for high level term; ³Rates for preferred term (PT; IBD for unspecified IBD); ⁴Rates for Novartis MedDRA Query term; ⁵Rates for standardized MedDRA query term – 'malignancies and unspecified tumour'; EAIR, exposure adjusted incidence rate per 100 pt-years; N, number of pts in the analysis

Table 2. Summary of SEC post-marketing safety

Exposure (PTY)	PSUR1 26Dec14 -25Jun15	PSUR2 26 Jun -25Dec15	PSUR3 26Dec15 -25Jun16	PSUR4 26Jun -25Dec16	PSUR5 26Dec16 -25Dec17	PSUR6 26Dec17 -25Dec18	Cumulative
	1838	7450	16871	28549	93744	137325	285811
	n (Reporting rate PTY)						
Serious infections	89 (4.8)	149 (2.0)	232 (1.4)	475 (1.7)	649 (0.7)	1841 (1.3)	3980 (1.4)
Malignancy	2 (0.1)	15 (0.2)	21 (0.1)	50 (0.2)	225 (0.2)	422 (0.3)	788 (0.3)
Total IBD	4 (0.2)	12 (0.2)	37 (0.2)	46 (0.2)	185 (0.2)	340 (0.3)	693 (0.2)
MACE	6 (0.3)	15 (0.2)	16 (0.1)	39 (0.1)	151 (0.2)	238 (0.2)	504 (0.2)

PSUR, periodic safety update report; PTY, pt-treatment years

Conclusion: In this long-term analysis across clinical trials and post-marketing surveillance, of pts with PsO, PsA and AS, SEC was well tolerated, with a safety profile consistent with previous reports.¹

Reference:

[1] Deodhar et al. Arthritis Research & Therapy (2019) 21:111.

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FRI0273

EFFECTIVENESS AND RETENTION RATE OF SECUKINUMAB FOR PSORIATIC ARTHRITIS AND AXIAL SPONDYLOARTHRITIS: REAL-LIFE DATA FROM THE ITALIAN LORHEN REGISTRY

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