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Background: EQUATOR (NCT03101670) was a Phase 2, double-blind, randomised placebo (PBO)- controlled trial of the preferential Janus kinase 1 inhibitor filgotinib (FIL) for the treatment of psoriatic arthritis (PsA); EQUATOR2 (NCT03320876) is the open-label extension (OLE).

Objectives: This post-hoc analysis assessed the effect of FIL on individual Psoriatic Arthritis Disease Activity Score (PASDAS) components; and the association between PASDAS disease activity (DA) levels and DA levels achieved for each PASDAS component and patient-reported outcomes (PROs) up to OLE Week (Wk) 100.

Methods: In EQUATOR, patients with active moderate-to-severe PsA were randomised 1:1 to oral FIL 200mg or PBO once daily (QD) for 16 wks.¹ At Wk 16, patients could continue into the 304-wk OLE, in which all patients received FIL 200mg QD. The proportions of patients with PASDAS of very low DA (VLDA; ≤ 1.9), LDA (>1.9 – <3.2), moderate DA (MoDA; ≥ 3.2 – <5.4), and high DA (HDA; ≥ 5.4) at core Wk 16 and OLE Wk 52 and 100 were assessed. The proportion with improved PASDAS status vs baseline (BL) at OLE Wk 52 and 100 was calculated. Percent change from BL in PASDAS components and PROs were assessed at core Wk 16 and OLE Wk 52 and 100 by PASDAS status (VLDA, LDA, other). Multivariate logistic regression analyses performed cross-sectionally identified PASDAS components and PROs associated with not achieving VLDA or LDA at core Wk 16 and OLE Wk 52 and 100; all analyses were observed cases.

Results: At OLE Wk 52, LDA and VLDA were achieved by 27.5% and 16.8% of randomised patients, respectively (44.3% combined). At OLE Wk 100, LDA and VLDA were achieved by 26.0% and 17.6% of patients (43.6% combined; Figure 1). Of patients with HDA at BL, 69% improved to MoDA/LDA/VLDA, <4% remained in HDA and 27% did not reach Wk 100; of those in MoDA at BL, 63% improved to VLDA/LDA, 11% remained stable, <4% worsened and 22% did not reach Wk 100. Patient Global Assessment of Disease Activity (PtGDA), Short Form-36 physical component scale (SF-36 PCS), Functional Assessment of Chronic Illness Therapy, and Health Assessment Questionnaire Disability Index were found to be important components/PRO measures in achieving VLDA vs LDA (Table 1). Logistic regression indicated that factors associated with not achieving LDA at Wk 52 were PtGDA (odds ratio [OR]: 1.20, 95% confidence interval [CI]: 1.07–1.35), physician GDA (PhGDA; OR: 1.58, 95% CI: 1.18–2.12), and SF-36 PCS (OR: 0.79, 95% CI: 0.67–0.95); PtGDA was associated with not achieving VLDA (OR: 1.30, 95% CI: 1.15–1.47).

Conclusion: The proportion of patients achieving PASDAS VLDA or LDA increased over time and remained stable between OLE Wk 52 and 100. Important factors in determining whether VLDA/LDA was met were PtGDA, PhGDA, and SF-36 PCS, although the low patient numbers is a limitation.

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Figure. Proportion of patients with VLDA, LDA, MoDA, and HDA at baseline, Core Week 16, OLE Week 52, and OLE Week 100

Proportions are based on the all randomised population
*Patients are presented according to original treatment in the core study. During the OLE all patients received filgotinib
†Missing includes patients who did not reach the timepoint or had a missing assessment
HDA, high disease activity; LDA, low disease activity; MoDA, moderate disease activity; OLE, open-label extension; VLDA, very low disease activity

Table 1. Mean % change from baseline in PASDAS components and PROs (observed cases)

	Core Wk 16 (FIL + PBO groups combined)			OLE Wk 52			OLE Wk 100		
	n=122			n=110			n=97		
	VLDA	LDA	Others	VLDA	LDA	Others	VLDA	LDA	Others
	n=8	n=22	n=92	n=22	n=36	n=52	(24%)	n=34	n=40
	(7%)	(18%)	(75%)	(20%)	(33%)	(47%)	(35%)	(41%)	
PhGDA	–93	–75	–44	–94	–82	–56	–96	–84	–54
PtGDA	–87	–69	–13	–86	–58	–24	–90	–57	–13
Tender joint count 68	–94	–80	–42	–99	–84	–64	–98	–87	–61
Swollen joint count 66	–99	–80	–64	–99	–96	–78	–99	–94	–80
LEI	–100	–86	–32	–96	–100	–78	–100	–99	–78
Dactylitis	–100	–100	–73	–100	–100	–97	–100	–100	–98
C-reactive protein	–66	–22	17	138*	–32	–25	–12	–13	24
SF-36 PCS	53	26	11	33	23	9	47	23	16
FACIT	119	50	32	97	51	34	99	46	36
HAQ-DI	–84	–68	–18	–85	–51	–18	–88	–45	–19
PASI	–84	–66	–29	–54	–59	–56	–49	–76	–42

Components or PRO measures in bold are those for which numerical differences between VLDA and LDA are greatest across timepoints*Due to outlier (3784)FACIT, Functional Assessment of Chronic Illness Therapy; HAQ-DI, Health Assessment Questionnaire Disability Index; LEI, Leeds Enthesitis Index; PASI, Psoriasis Area Severity Index; PhGDA, Physician Global Assessment of Disease Activity; PtGDA, Patient Global Assessment of Disease Activity; SF-36 PCS, Short Form-36 physical component summary; (V)LDA, (very) low disease activity

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POS1050 SECUKINUMAB LEADS TO IMPROVEMENT ACROSS PSORIATIC ARTHRITIS MANIFESTATIONS OVER 2 YEARS REGARDLESS OF PREVIOUS EXPOSURE TO A TNF INHIBITOR: A POST HOC ANALYSIS OF FUTURE 5

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Table 1. Achievement of Key Outcomes Across PsA Manifestations at Week 104 Among TNFi-IR and TNFi-Naive Patients Treated With SEC

	SEC 300 mg		SEC 150 mg ^a		SEC 150 mg No Load ^b		PBO-SEC 300 mg		PBO-SEC 150 mg ^c	
Outcomes, n/M (%)	TNFi-naive n=154	TNFi-IR n=68	TNFi-naive n=153	TNFi-IR n=67	TNFi-naive n=157	TNFi-IR n=65	TNFi-naive n=109	TNFi-IR n=44	TNFi-naive n=114	TNFi-IR n=39
TJC/SJC resolution	51/140 (36.4)	19/51 (37.3)	46/136 (33.8)	11/46 (23.9)	53/125 (42.4)	14/43 (32.6)	40/90 (44.4)	11/31 (35.5)	32/96 (33.3)	10/28 (35.7)
Resolution of dactylitis	42/48 (87.5)	11/16 (68.8)	37/43 (86.0)	16/19 (84.2)	56/62 (90.3)	11/13 (84.6)	35/41 (85.4)	5/7 (71.4)	30/33 (90.9)	10/12 (83.3)
Resolution of enthesitis	70/88 (79.5)	22/30 (73.3)	70/85 (82.4)	24/32 (75.0)	50/69 (72.5)	16/26 (61.5)	37/50 (74.0)	12/17 (70.6)	39/56 (69.6)	14/20 (70.0)
mNAPSI75	61/73 (83.6)	15/26 (57.7)	66/76 (86.8)	16/23 (69.6)	61/80 (76.3)	13/18 (72.2)	42/51 (82.4)	13/17 (76.5)	34/64 (53.1)	7/14
PASI100	34/68 (50.0)	14/29 (48.3)	41/85 (48.2)	5/19 (26.3)	33/73 (45.2)	4/18 (22.2)	23/45 (51.1)	9/18 (50.0)	19/46 (41.3)	(50.0) 6/13 (46.2)

IR, inadequate responder; M, number of evaluable patients; mNAPSI, modified Nail Psoriasis Severity Index; PASI, Psoriasis Area and Severity Index; PBO, placebo; SEC, secukinumab; TJC/SJC resolution, 0 tender/swollen joints; TNFi, tumor necrosis factor inhibitor. ^a Includes 53 TNFi-naive and 23 TNFi-IR patients with dose escalation. ^b Includes 58 TNFi-naive and 19 TNFi-IR patients with dose escalation. ^c Includes 40 TNFi-naive and 12 TNFi-IR patients with dose escalation.

Background: The goal of treating psoriatic arthritis (PsA) is to achieve very low disease activity or remission across disease manifestations. In the phase 3 FUTURE 5 study (NCT02404350), patients receiving secukinumab (SEC) demonstrated sustained clinical improvements across PsA manifestations through Week 104.¹ However, the effect of previous tumor necrosis factor inhibitor (TNFi) exposure on achievement of remission across PsA manifestations was not explored.

Objectives: To report exploratory efficacy analyses of SEC at Week 104 on stringent endpoints across PsA manifestations in patients who were TNFi naive or inadequate responders (TNFi-IR).

Methods: Patient data from FUTURE 5 were stratified by previous TNFi exposure and analyzed by treatment arm. At Week 104, patients received SEC 300 or 150 mg with subcutaneous loading dose (LD), SEC 150 mg without LD, or had received placebo up to Week 16 and were switched to SEC 300 or 150 mg between Weeks 16 or 24 based on tender and swollen joint count response. Patients with suboptimal clinical response to SEC 150 mg could escalate to SEC 300 mg after Week 52 per investigator judgment.² Exploratory efficacy analyses at Week 104 included resolution of TJC/SJC (0 tender/swollen joints), resolution of enthesitis and dactylitis, 75% improvement in the modified Nail Psoriasis Severity index (mNAPSI75), 100% improvement in the Psoriasis Area and Severity Index (PASI100), very low disease activity (VLDA), and Disease Activity in Psoriatic Arthritis (DAPSA) remission. Descriptive statistics are provided for each endpoint using an observed-case approach.

Results: Regardless of previous TNFi exposure, SEC-treated patients achieved several stringent endpoints across PsA domains, including TJC/SJC resolution, resolution of dactylitis/enthesitis, mNAPSI75, and PASI100 at Week 104 (Table 1). TNFi-naive patients generally experienced greater improvements than TNFi-IR patients (Table 1 above). Similar trends were observed for achievement of VLDA and DAPSA remission at Week 104 (Figure 1).

Conclusion: SEC treatment resulted in sustained achievement of stringent endpoints across key PsA manifestations through Week 104 in both TNFi-naive and TNFi-IR patients, with generally greater clinical responses among TNFi-naive patients.

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Figure. Proportion of Patients Achieving (A) VLDA and (B) DAPSA Remission at Week 104

DAPSA, Disease Activity in Psoriatic Arthritis; IR, inadequate responders; NL, no subcutaneous loading dose; PBO, placebo; SEC, secukinumab; VLDA, very low disease activity based on body surface area.

Figure 1.

POS1051 SECUKINUMAB IMPROVES PHYSICAL FUNCTION AND INHIBITS STRUCTURAL DAMAGE IN PsA PATIENTS WITH SUSTAINED REMISSION OR LOW DISEASE ACTIVITY: RESULTS FROM A PHASE 3 STUDY

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Background: Disease Activity Index for Psoriatic Arthritis (DAPSA) or the minimal disease activity (MDA) are considered for defining remission (REM) or low disease activity (LDA) in secukinumab (SEC) treated patients (pts) with PsA (Psoriatic Arthritis).¹ Currently, limited SEC data are available on pts with PsA achieving sustained REM in clinical trials or real-world evidence, using these stringent criteria.

Objectives: To report an exploratory analysis on achievement of sustained REM/LDA in pts with PsA treated with SEC and impact on structural outcomes, physical function and health-related quality of life (HRQoL) in the FUTURE 5 study (NCT02404350).