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FRI0339

LONG-TERM EFFICACY OF THE ORAL SELECTIVE JANUS KINASE 1 INHIBITOR FILGOTINIB IN PSORIATIC ARTHRITIS: WEEK 52 RESPONSE PATTERNS IN INDIVIDUAL PATIENTS FROM AN OPEN-LABEL EXTENSION (OLE) STUDY (EQUATOR2)

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Background: EQUATOR (NCT03101670) was a 16-week, Phase 2, multicenter, double-blind, placebo-controlled, randomized controlled trial (RCT) of filgotinib in patients with active psoriatic arthritis.[1] Filgotinib demonstrated rapid efficacy compared with placebo across multiple domains, including the primary endpoint of Week 16 American College of Rheumatology (ACR) 20 response.[1] Patients completing the RCT could join an ongoing 148-week OLE (EQUATOR2; NCT03320876).

Objectives: In this prespecified interim analysis at Week 52 of the OLE, individual patient responses with respect to disease activity were evaluated.

Methods: Placebo-treated RCT patients switched to filgotinib (200 mg once daily) at Week 16 and entered the OLE; patients previously assigned to filgotinib continued. Individual response patterns at Week 52 of the OLE were evaluated for ACR20/50/70, Psoriatic Arthritis Disease Activity Score (PASDAS) low disease activity (LDA), minimal disease activity (MDA), and MDA/very low disease activity (VLDA).

Results: 124 patients (95%) completed EQUATOR; 122 (93%) enrolled in the OLE. At Week 52, 11 patients (9%) had discontinued treatment in the OLE. Median (range) exposure to filgotinib was 66.0 (0.4–104.1) weeks. In patients originally assigned to filgotinib, sustained efficacy was seen through to OLE Week 52 for ACR20, 50, and 70; PASDAS LDA; MDA (**Table;** Figure 1**a**); and MDA/VLDA. In total, 77% and 93% of those achieving MDA and ACR50 response in the RCT period maintained this at Week 52 (**Table**). A substantial proportion of RCT non-responders also achieved a treatment response in the OLE, meeting MDA and ACR50 criteria (22% and 37%, respectively; **Table**). Response patterns in the OLE were similar regardless of prior RCT treatment. In total, at Week 52 of the OLE, 33.6% of patients achieved MDA response (Figure 1**a**); 55.0% achieved ACR50 response. Figure 1**b** shows individual patient response over time for MDA.

Conclusion: Data from this 52-week OLE interim analysis suggest that further improvement in disease activity can be expected with filgotinib beyond 16 weeks in patients with active psoriatic arthritis. Sustained efficacy was demonstrated across several measures of disease activity, including MDA and ACR50.

References:

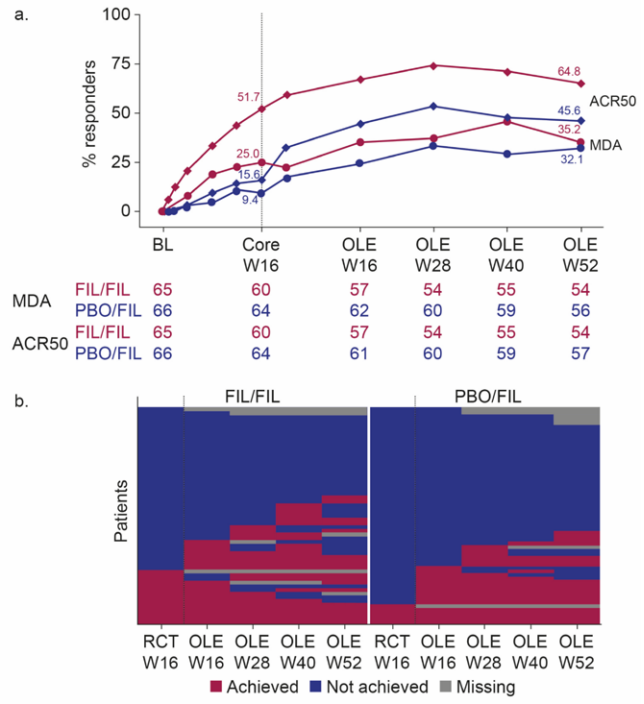
[1] Mease P, et al. Lancet 2018;392:2367–77.

Table. Responders at Week 52 of the OLE, by treatment and previous RCT responder status (observed cases).

Treatment	Filgotinib (N=59) → Filgotinib (N=54)[a]		Placebo (N=63) → Filgotinib (N=57)[a]	
n/N, %	OLE responders/ RCT responders	OLE responders/RCT non-responders	OLE responders/ RCT responders	OLE responders/RCT non-responders
ACR20	40/47 (85.1)	5/7 (71.4)	17/18 (94.4)	27/38 (71.1)
ACR50	25/27 (92.6)	10/27 (37.0)	5/8 (62.5)	21/49 (42.9)
ACR70	10/13 (76.9)	12/41 (29.3)	3/4 (75.0)	12/53 (22.6)
PASDAS LDA[b]	19/21 (90.5)	12/32 (37.5)	5/6 (83.3)	21/48 (43.8)
MDA	10/13 (76.9)	9/41 (22.0)	4/5 (80.0)	14/51 (27.5)

[a]Indicates number remaining at OLE Week 52 interim analysis, after dropouts
[b]PASDAS information was not available for one patient at Week 16 of the RCT

Figure 1. Patients achieving ACR50 and MDA over time (a) and MDA per patient over time (b).



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FRI0340

COMPARISON OF SECUKINUMAB VERSUS ADALIMUMAB EFFICACY ON SKIN OUTCOMES IN PSORIATIC ARTHRITIS: 52-WEEK RESULTS FROM THE EXCEED STUDY

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Background: Psoriatic arthritis (PsA) is a heterogeneous disease comprising musculoskeletal and dermatological manifestations, especially plaque psoriasis.[1] Secukinumab (SEC), an IL-17A inhibitor, provided significantly greater PASI 75/100 responses in a head-to-head trial *versus (vs.)* etanercept, a TNF inhibitor, in patients (pts) with moderate-to-severe plaque psoriasis.[2] The objective of the EXCEED study (NCT02745080) was to investigate whether SEC is superior to

adalimumab (ADA), a TNF inhibitor, as monotherapy in biologic-naive active PsA pts with active plaque psoriasis (defined as having at least one psoriatic plaque of ≥2 cm diameter or nail changes consistent with psoriasis or documented history of plaque psoriasis).

Objectives: To report the pre-specified skin outcomes from the EXCEED study in the subset of pts with at least 3% body surface area (BSA) affected with psoriasis at baseline.

Methods: Head-to-head, phase-3b, randomised, double-blind, active-controlled, multicentre, parallel-group trial: pts were randomised to receive SEC 300 mg subcutaneous at baseline, Week 1-4, followed by dosing every 4 weeks (q4w) until Week 48 or ADA 40 mg subcutaneous at baseline followed by same dosing q2w until Week 50. The primary endpoint was superiority of SEC *vs.* ADA on ACR20 response at Week 52. Pre-specified outcomes included the proportion of pts achieving a combined ACR50 and PASI 100 response, PASI 100 response, and absolute PASI score ≤3. Missing data was handled using multiple imputation.

Results: 853 pts were randomised to receive SEC (n=426) or ADA (n=427). At baseline, there were 215 and 202 pts having at least 3% BSA affected with psoriasis in the SEC and ADA groups, respectively. A higher proportion of patients achieved simultaneous improvement in ACR50 and PASI 100 response with SEC *vs.* ADA (30·7% *vs.* 19·2%; P=0·0087 [Figure]). Higher efficacy was demonstrated for SEC *vs.* ADA for PASI 100 responses and for the proportion of pts achieving absolute PASI score ≤3 (Table).

Conclusion: In this pre-specified analysis, SEC provided higher responses compared to ADA in achievement of simultaneous improvement of joint and skin disease (combined ACR50 and PASI 100 response) and in skin specific endpoints (PASI 100 and PASI score ≤3) at Week 52.

References:

[1] Coates LC and Helliwell PS. *Clinical Med*.2017;17:65–70.
[2] Langley RG et al. *N Engl J Med.* 2014;371:326–38.

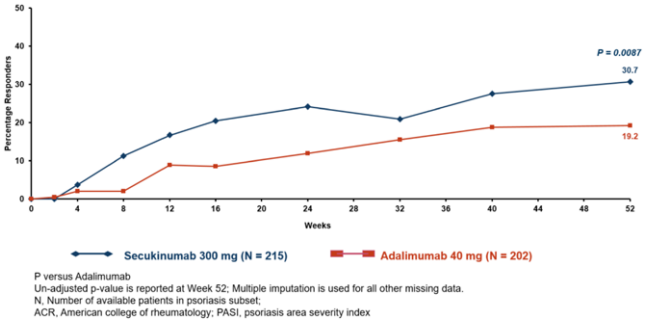

Figure. Combined ACR50 and PASI 100 Response through Week 52

Table. Skin Specific Outcomes at Week 52

Endpoints, data is presented as % response	SEC 300 mg (N = 215)	ADA 40 mg (N = 202)	P-value (unadjusted)
PASI 100	46·0	29·7	0·0007
Absolute PASI score ≤3	79·2	65·0	0·0015

P value vs. adalimumab; Unadjusted P values are presented
N, number of patients in psoriasis subset
Multiple imputation was used for handling missing data
ADA, adalimumab; BSA, body surface area; PASI, psoriasis area severity index; SEC, secukinumab

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FRI0341

RISK FACTORS FOR AXIAL INVOLVEMENT IN EARLY PSORIATIC ARTHRITIS

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Background: Axial Involvement in psoriatic arthritis (PsA) is quite common [1]. Predictors of axial involvement at early-stage of disease haven't been sufficiently studied.

Objectives: To identify predictors of axial involvement in PsA patients (pts) at early-stage of disease.

Methods: 95 patients (pts) (M/F–47/48) with early PsA fulfilling the CASPAR criteria were included. All pts had peripheral arthritis for≤2 years; no inflammatory back pain (IBP) pts were specifically selected. Mean (Me) age 36.5±10.7 yrs, disease duration 12.2±10.3 mo. Pts underwent standard clinical examination of PsA activity. Me disease activity indexes DAS=4.0±1.4, DAS28=4.2±1.1, BASDAI=4.5±1.6; Me pts global disease activity VAS 56.9±17.1. All patients were evaluated for the presence of IBP by ASAS criteria, underwent sacroiliac joints (SIJs) X-ray (pelvic radiographs) and HLA B27 antigen status study. MRI of SIJs was performed in 79 pts, regardless of IBP presence, on Signa Ovation 0.35T. Radiographic sacroiliitis (R-SI) was identified according to New York criteria (unilateral grade≥3 or bilateral grade≥2). Bone marrow edema/ osteitis on MRI (STIR) was considered active MRI sacroiliitis (MRI-SI). X-ray and MRI results were evaluated by an independent reader. IBP was observed in 63 (66.3%) cases, MRI-SI in 28 of 79 (35.4%) examined cases, R-SI in 29 (30.5%) cases. Skin lesion severity was evaluated as body surface area (BSA) affected: minor at <3%, mild at 3-10%, severe at >10%. Pts were split into 2 groups (gr.): those with axial involvement (axPsA), that is with IBP and/or R-SI and/or MRI-SI; and those without axial involvement (having only peripheral PsA [pPsA]).The axPsA gr. included 65 (68.4%) cases, the pPsA gr. 30 (31.6%) cases. Multi-dimensional step-by-step discriminant analysis was used to identify a group of features that are more typical for the axPsA patients.