REFERENCE:

[1] Ometto F., et al. Treatment adherence in rheumatoid arthritis italian patients using a validated version of the 5-item compliance questionnaire for rheumatology (I-CQR5). EULAR18-4294.

Univariate analysis. Demographics and clinical variables according to high and low adherence to treatment defined by I-CQR5.				
	Total	HA	LA	p value
No.	193	79 (40.9)	114 (59.1)	
HA, n (%)	79 (40.9)	-	-	-
Females (%)	142 (73.4)	52 (65.8)	90 (80.4)	0.024*
Age, years, median (IQR)	57 (46-65)	54 (50-62)	57 (51-66.3)	0.491
BMI, median (IQR)	24 (22-28)	25 (23-28)	24 (21-27.8)	0.545
Smokers, n (%)	28 (17.6)	12 (15.1)	16 (15.7)	0.394
Employed, n (%)	81 (47.1)	41 (64.1)	40 (37)	0.001*
Education level				0.147
Primary school, n (%)	20 (11)	8 (10.3)	12 (11.5)	
Median school, n (%)	65 (33.7)	21 (26.9)	44 (42.3)	
Secondary school, n (%)	88 (47.4)	34 (43.8)	54 (52.2)	
University, n (%)	29 (15.9)	15 (19.2)	14 (13.5)	
Primary/middle school education, n (%)	85 (46.7)	29 (37.2)	56 (53.8)	0.026*
Social status				0.567
Living with parents and family, n (%)	13 (8.7)	5 (9.3)	8 (8.3)	
Living alone, n (%)	16 (10.7)	6 (11.1)	10 (10.4)	
Living with partner and family, n (%)	113 (75.3)	38 (70.4)	75 (78.1)	
Other, n (%)	6 (4)	4 (7.4)	2 (2.1)	
Positive RF and/or ACPA, n (%)	79 (42.2)	27 (34.6)	52 (47.7)	0.074*
Disease duration, years, median (IQR)	15 (9-21)	14 (10-21)	15 (9-21.5)	0.762
Fibromyalgia, n (%)	38 (20.8)	12 (15.6)	26 (24.5)	0.141
csDMARD treatment, n (%)	57 (30.5)	19 (24.4)	38 (34.9)	0.124
Methotrexate, n (%)	41 (21.9)	16 (20.5)	25 (22.9)	0.693
Leflunomide, n (%)	12 (6.4)	3 (3.8)	9 (8.3)	0.225
Other DMARD, n (%)	7 (3.7)	0 (0)	7 (6.4)	0.023
bDMARD treatment, n (%)	193 (100)	79 (100)	114 (100)	-
bDMARD				0.541
Abatacept, n (%)	13 (8.7)	8 (7)	5 (6.3)	
Adalimumab, n (%)	35 (18.1)	19 (16.7)	16 (20.3)	
Anakinra, n (%)	11 (6.7)	7 (6.1)	4 (5.1)	
Certolizumab pegol, n (%)	15 (7.8)	9 (7.9)	6 (7.6)	
Etanercept, n (%)	101 (52.3)	62 (54.4)	39 (49.4)	
Golimumab, n (%)	8 (4.1)	6 (5.3)	2 (2.5)	
Tocilizumab, n (%)	10 (5.2)	3 (2.6)	7 (8.9)	
bDMARD treatment administered < 1 week, n (%)	110 (57)	43 (54.4)	67 (62.8)	0.549
Low dose bDMARD, n (%)	82 (42.7)	29 (49.4)	43 (37.7)	0.091*
Previous bDMARD failure treatment, n (%)	62 (38.5)	29 (38.7)	33 (38.4)	0.969
Duration bDMARD treatment, months, median (IQR)	88 (45-61.8)	88 (47-130)	86 (41.5-120)	0.992
Associated treatment, n (%)	57 (30.5)	19 (24.4)	38 (34.9)	0.124
Disease duration > 24 months, n (%)	149 (83.7)	63 (82.9)	86 (84.3)	0.8
PON daily dose, median (IQR)	1.5 (0-5)	0 (0-1)	2.5 (0-5)	0.13
NSAIDs, n (%)	111 (66.1)	47 (67.1)	64 (65.3)	0.804
Painkillers, n (%)	50 (31.4)	22 (31.9)	28 (31.1)	0.917
Concomitant chronic treatment, n (%)	91 (49.7)	38 (50.7)	53 (49.1)	0.832
DAS28, median (IQR)	2.3 (1.8-2.8)	2.3 (1.7-2.8)	2.4 (1.8-3.0)	0.441
Remission, n (%)	101 (52.9)	39 (49.4)	62 (55.4)	0.414
Low disease activity, n (%)	174 (91.1)	73 (92.4)	101 (90.2)	0.595
Patient-VAS, median (IQR)	38 (20-66)	30 (10-50)	45 (28-69)	0.034
Physician-VAS, median (IQR)	10 (5-15)	10 (0-15)	10 (6-20)	0.988
HAQ, median (IQR)	0.6 (0.1-1.1)	0.5 (0-1.1)	0.8 (0.3-1.1)	0.14
Disease flares, median (IQR)	11 (2-22)	5 (3-33)	6 (2-22)	0.433
No. of assessments per year, median (IQR)	4 (3-4)	4 (3-4)	4 (3-4)	0.98
Distance from clinic, km, median (IQR)	32 (18-50)	30 (20-50)	35 (18-50)	0.948

Table. Multivariate regression analysis. Factors associated with HA to anti-rheumatic treatment according to I-CQR5.

	OR (95% C.I.)	p
Male gender	2.05 (0.9-4.66)	0.086
Employment	2.89 (1.3-6.44)	0.009
Patient-VAS (per 10-unite increase)	0.95 (0.83-1.09)	0.453
Model constant		0.035

OR odds ratio, C.I. confidence interval, VAS visual analogic scale.

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SAFETY AND EFFICACY OF FILGOTINIB IN ACTIVE RHEUMATOID ARTHRITIS BY PRIOR BIOLOGICAL DMARD EXPOSURE IN PATIENTS WITH PRIOR INADEQUATE RESPONSE OR INTOLERANCE TO BIOLOGICAL DMARDS (bDMARD-IR)

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Background: Filgotinib (FIL), an oral selective Janus kinase 1 (JAK1) inhibitor, significantly improved the signs and symptoms of rheumatoid arthritis (RA) with a favorable safety profile in a global phase 3 study in bDMARD-IR patients with active RA (FINCH2).¹

Objectives: To assess the safety and efficacy of FIL in the FINCH2 study by the number and type of prior bDMARDs.

Methods: FINCH2 enrolled 449 bDMARD-IR patients with moderate-to-severe active RA. Patients were randomized 1:1:1 to FIL 200 mg, FIL 100 mg or placebo (PBO) on a background of csDMARDs for 24 weeks. In this prespecified subgroup analysis, efficacy and safety were analyzed according to the number (<3 vs ≥3) of previous bDMARDs used.

Results: 448 patients received ≥1 dose of study drugs. Of these, 343 were previously exposed to <3 bDMARDs, while 105 were previously exposed to ≥3 bDMARDs. Table 1 shows demographics and baseline (BL) characteristics of patients in these 2 groups; efficacy and safety parameters (Table 2) were similar for both groups. There were no cases of opportunistic infection, active tuberculosis, malignancy, gastrointestinal perforation, or death.

Table 1. BL Demographics and characteristics

	<3 bDMARDs (n=343)			≥3 bDMARDs (n=105)		
	FIL 200 (n=110)	FIL 100 (n=119)	PBO (n=114)	FIL 200 (n=37)	FIL 100 (n=34)	PBO (n=34)
Female, n (%)	90 (82)	92 (77)	93 (82)	30 (81)	27 (79)	28 (82)
Mean (SD) age, yrs	54 (13)	55 (13)	56 (12)	59 (9)	54 (9)	56 (12)
Concurrent steroids, n (%)	46 (42)	49 (41)	54 (47)	22 (60)	19 (56)	17 (50)
Concurrent MTX, n (%)	98 (89)	101 (85)	96 (84)	26 (70)	26 (77)	20 (59)
Mean (SD) DAS28 (CRP)	6.0 (1.0)	5.8 (1.0)	5.9 (0.9)	5.8 (1.0)	6.1 (1.0)	5.9 (0.9)
Mean (SD) HAQ-DI	1.66 (0.65)	1.62 (0.70)	1.63 (0.65)	1.84 (0.66)	1.72 (0.61)	1.74 (0.57)
Mean (SD) hsCRP (mg/L)	17.04 (16.80)	21.82 (28.49)	16.08 (19.16)	17.70 (22.36)	20.31 (27.58)	17.56 (15.37)

Table 2. Key week 24 efficacy and safety outcomes

	<3 bDMARDs (n=343)			≥3 bDMARDs (n=105)		
	FIL 200 (n=110)	FIL 100 (n=119)	PBO (n=114)	FIL 200 (n=37)	FIL 100 (n=34)	PBO (n=34)
ACR20 n (%) ^a	Δ34.9%	Δ21.2%		Δ35.2%	Δ17.6%	
DAS28(CRP)≤3.2 n (%) ^a	Δ27.3%	Δ15.8%		Δ29.0%	Δ20.6%	
DAS28(CRP)≤2.6 n (%) ^a	Δ19.6%	Δ12.9%		Δ15.7%	Δ17.6%	
HAQ-DI mean CFB (SD)	-0.74 (0.631) [‡]	-0.61 (0.668)*	-0.42 (0.618)	-0.77 (0.596) [‡]	-0.54 (0.635)	-0.44 (0.525)
SF-36 PCS mean CFB (SD)	9.4 (8.45) [‡]	8.9 (8.72)*	6.4 (8.44)	9.4 (7.65)	9.1 (7.36)	7.2 (5.44)
FACIT-Fatigue mean CFB (SD)	11.3 (11.99) [‡]	9.7 (10.44)*	6.7 (10.68)	12.6 (10.78) [‡]	10.2 (10.42) [‡]	8.4 (8.12)
TEAE	75 (68.2%)	73 (61.3)	76 (66.7%)	27 (73.0%)	24 (70.6%)	24 (70.6%)
TEAE leading to study drug discontinuation	4 (3.6%)	3 (2.5%)	2 (1.8%)	1 (2.7%)	3 (8.8)	1 (2.9%)

CFB, change from BL. *p<0.05, †p<0.01, ‡p<0.001; Δ, difference vs PBO.

^aFIL values are PBO-corrected.

Conclusion: In bDMARD-IR patients with active RA, FIL treatment for 24 weeks significantly improved the signs and symptoms of RA with a favorable safety profile; notably, efficacy and safety results were similar for patients with <3 or ≥3 prior bDMARDs.

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