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FILGOTINIB IN PATIENTS WITH RHEUMATOID ARTHRITIS AND PRIOR INADEQUATE RESPONSE OR INTOLERANCE TO BIOLOGICAL DMARDS (bDMARD-IR) BY RACE & GEOGRAPHIC REGION

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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) in the phase 3 FINCH2 study in bDMARD-IR patients with active RA.¹

Objectives: To evaluate the efficacy and safety of FIL by geography and race in FINCH2.

Methods: FINCH2 enrolled 449 bDMARD-IR patients with active RA, who were randomized in a 1:1:1 manner to receive FIL 200 mg, FIL 100 mg, or placebo (PBO) on a background of csDMARDs for 24 weeks. In this prespecified subgroup analysis, patient and disease characteristics and treatment effects were analyzed by race and geographic region (Region 1: AU, BE, FR, DE, IS, IT, NL, KR, ES, CH, UK, US; Region 2: HU, CZ, PL; Region 3: AR, PR, MX; Region 4: JP).

Results: 448 patients received ≥ 1 dose of study drug; they were 80.4% female, with a mean [SD] age of 56 [12.2] years, and 23.4% had received ≥ 3 prior bDMARDs. Baseline characteristics were similar across regions and race. The primary endpoint and all key secondary endpoints were met in the primary analysis.¹ Efficacy and safety parameters by geography and race are shown below. There were 2 MACE (white/Region 1, 1 FIL 100/1 PBO), 4 cases of uncomplicated herpes zoster (2 black/1 white/1 Asian; 3 Region 1/1 Region 4, 2 FIL 200/2 FIL 100), and 1 VTE (retinal vein occlusion, white/Region 1/FIL 200), but no cases of DVT/PE, opportunistic infection, active tuberculosis, malignancy, gastrointestinal perforation, or death.

Table 1. Week 24 key efficacy and safety measures by geographic region.

	Regimen	N ¹ =	ACR20; % ²	DAS28(CRP) <2.6; % ²	CFB HAQ-DI	TEAE; %	SAE; %
Region 1	FIL 200	111	67 ²	31 ²	-0.7 (0.6) ²	73	5
	FIL 100	110	48 ²	24	-0.6 (0.7) ²	66	6
	PBO	110	32	14	-0.4 (0.6)	70	5
Region 2	FIL 200	12	75	25	-0.7 (0.7)	58	0
	FIL 100	12	75	33	-0.6 (0.5)	75	17
	PBO	11	46	9	-0.5 (0.6)	73	0
Region 3	FIL 200	12	67	17	-1.2 (0.6)	42	8
	FIL 100	16	81	38	-1.0 (0.7)	44	0
	PBO	14	64	14	-0.8 (0.6)	36	0
Region 4	FIL 200	12	92 ²	50 ²	-0.7 (0.5) ²	75	0
	FIL 100	15	60 ²	27	-0.5 (0.7) ²	60	0
	PBO	13	15	0	-0.1 (0.6)	77	0

¹n's for HAQ-DI at week 24 were different. ²Nonresponder imputation. *p<0.05, ²p<0.01, ³p<0.001 vs PBO. CFB, change from baseline as mean (SD); SAE, serious adverse events; TEAE, treatment-emergent adverse events.

Table 2. Week 24 key efficacy and safety measures by race.

	Regimen	N ¹ =	ACR20; % ²	DAS28(CRP) <2.6; % ²	CFB HAQ-DI	TEAE; %	SAE; %

White	FIL 200	110	67 ²	30 ²	-0.7 (0.6) ²	71	5
	FIL 100	109	49 ²	25	-0.5 (0.6)	63	6
	PBO	97	34	16	-0.5 (0.6)	66	4
Black	FIL 200	14	57	21	-0.7 (0.6) ²	57	0
	FIL 100	12	67	17	-0.6 (0.7)	67	8
	PBO	21	38	14	-0.2 (0.5)	67	0
Asian	FIL 200	15	93 ²	47 ²	-0.8 (0.6) ²	73	0
	FIL 100	20	60 ²	30 ²	-0.6 (0.7) ²	65	0
	PBO	15	13	0	-0.1 (0.5)	80	7

¹n's for HAQ-DI at week 24 were different. ²Nonresponder imputation. *p<0.05, ²p<0.01, ³p<0.001 vs PBO. CFB, change from baseline as mean (SD); SAE, serious adverse events; TEAE, treatment-emergent adverse events. **Conclusion:** FIL demonstrated consistent safety and efficacy in bDMARD-IR patients with RA regardless of geography or race.

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[1] Genovese MC, et al. ACR 2018. Abstract L06.

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