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Efficacy and Safety of Filgotinib in Methotrexate-Naïve Patients with Rheumatoid Arthritis: FINCH 3 52-Week Results

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Introduction

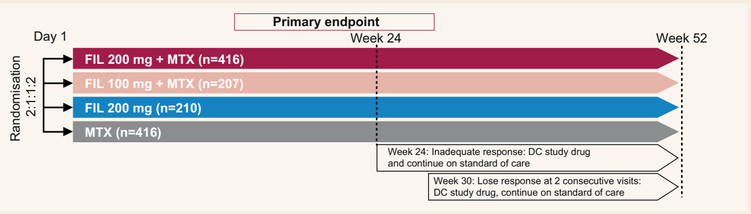
- Filgotinib – an oral, selective Janus kinase 1 inhibitor – is effective and well tolerated in patients with rheumatoid arthritis (RA) with prior inadequate response to methotrexate (MTX) (FINCH 1; NCT02889796) and biologic disease-modifying antirheumatic drug (bDMARD) exposure (FINCH 2; NCT02873936)[1,2]
- FINCH 3 (NCT02886728) compared the efficacy and safety of filgotinib with and without MTX in MTX-naïve patients with active RA vs. MTX monotherapy
  - Filgotinib 200 mg + MTX was superior to MTX monotherapy for the primary outcome, American College of Rheumatology criteria (ACR20) at Week 24[3]
  - At Week 24, patients receiving filgotinib 200 mg or 100 mg with MTX achieved greater improvement in change from baseline in Health Assessment Questionnaire-Disability Index (HAQ-DI) and 28-joint Disease Activity Score with C-reactive protein (DAS28[CRP]) <2.6 response rates at Week 24 vs. MTX monotherapy
- Treat-to-target goals for RA include Boolean and Clinical Disease Activity Index (CDAI)-based remission[4]
- This analysis presents updated 52-week results from FINCH 3

Methods

Study design and patients

- This global, Phase 3, double-blind, active-controlled 52-week trial randomised MTX-naïve patients with active RA 2:1:1:2 to oral filgotinib 200 mg once daily + MTX, filgotinib 100 mg + MTX, filgotinib 200 mg monotherapy or MTX ≤20 mg weekly (**Figure 1**)
  - Patients had ≥1 of the following: ≥1 joint erosions per central reading on radiographs of the hands, wrists or feet; positive serum test for rheumatoid factor (RF) or anti-cyclic citrullinated peptide (anti-CCP) antibodies; or serum C-reactive protein (CRP) level ≥4 mg/L
  - Prior exposure to MTX was limited to ≤3 doses ≤25 mg each, with the last >28 days prior to study start
  - Randomisation was stratified by geographic region and presence of RF or CCP antibodies at screening
- At Week 24, patients with <20% improvement from baseline in swollen joint count (SJC) and tender joint count (TJC) discontinued study drug and received standard of care
  - At Weeks 30–52, patients with <20% improvement in SJC and TJC for 2 consecutive visits discontinued study drug and received standard of care
- Efficacy assessments included ACR20/50/70 response rates; proportion achieving DAS28(CRP) <2.6, CDAI ≤2.8, Simplified Disease Activity Index ≤3.3, and Boolean remission; and change from baseline in HAQ-DI and modified total Sharp/van der Heijde Score (mTSS)
- Safety was assessed with treatment-emergent adverse events (TEAEs) and graded laboratory abnormalities

Figure 1. FINCH 3 study design



Response was at least 20% improvement in SJC66 and TJC68 from baseline
DC: discontinue; FIL: filgotinib; MTX: methotrexate; SJC66: swollen joint count of 66; TJC68: tender joint count of 68

Statistical analysis

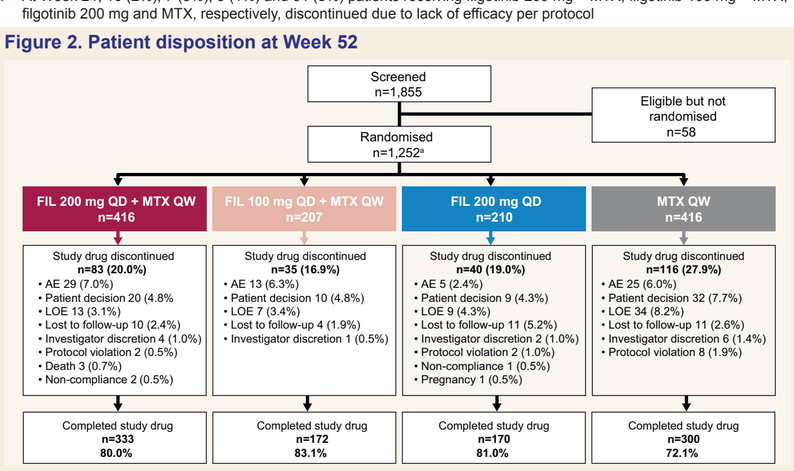
- Baseline characteristics were summarised using descriptive statistics
- TEAEs were summarised as n (%) and exposure-adjusted incidence rates (EAIR) per 100 patient-years of exposure (PYE)
  - EAIR were calculated using a Poisson regression model including treatment with an offset of natural log of exposure time
- Treatment effect for filgotinib vs. MTX on binary endpoints was evaluated using a logistic regression model including treatment and stratification factors; missing data were imputed as non-responders
- Changes from baseline in continuous endpoints were compared using a mixed-effect model for repeated measures with treatment, visit, treatment by visit interaction, stratification factors and baseline value included as fixed effects and patient as a random effect; missing data were not imputed
  - mTSS change from baseline at Week 52 included data from Campaign A (all radiographs through Week 24) and Campaign B (radiographs through Week 52 including re-reading of baseline and Week 24 radiographs), and the model included an additional random effect for difference between campaigns
- All Week 52 results and CDAI, SDAI and Boolean remission were not adjusted for multiple comparisons, and nominal p-values are reported

Results

Patient population

- Of 1,249 patients treated in FINCH 3, 975 (78.1%) received study drug through Week 52 (**Figure 2**)
- Discontinuation due to adverse events (AEs) was lowest for patients receiving filgotinib 200 mg monotherapy
- At Week 24, 10 (2%), 7 (3%), 3 (1%) and 31 (8%) patients receiving filgotinib 200 mg + MTX, filgotinib 100 mg + MTX, filgotinib 200 mg and MTX, respectively, discontinued due to lack of efficacy per protocol

Figure 2. Patient disposition at Week 52



[a] 3 patients were randomised but not dosed; 1 to FIL 200 mg + MTX and 2 to MTX monotherapy
AE: adverse event; FIL: filgotinib; LOE: loss of efficacy; MTX: methotrexate; QD: once daily; QW: once weekly

- In general, demographics and disease characteristics were similar across treatments (**Table 1**)
- The majority of patients (77%) were female, mean age was 53 years, median duration of RA diagnosis was 0.4 years and 77% of patients were DMARD-naïve
- In total, 41% of patients were from the USA, Spain, Germany, South Korea, Canada, Belgium, South Africa, Australia, New Zealand, the UK, Italy, Ireland and Israel; 36% were from India, Poland, Ukraine, Bulgaria, Russia, Czech Republic, Hungary, Serbia, Romania and Slovakia; 13.6% were from Mexico, Argentina and Chile; 3.6% were from Taiwan, Thailand, Malaysia and Hong Kong; and 5.7% were from Japan
- Baseline characteristics were consistent with active RA.[5] Baseline mean (standard deviation [SD]) DAS28(CRP) was 5.7 (1.0), 77% of patients were RF or anti-CCP positive and 94% of patients had at least 1 erosion
- At Week 24, mean (SD) MTX dose was 18.3 (3.19) mg for patients receiving filgotinib 200 mg + MTX, 18.1 (3.49) mg for filgotinib 100 mg + MTX and 18.4 (3.21) mg for MTX

Table 1. Baseline demographics and disease characteristics

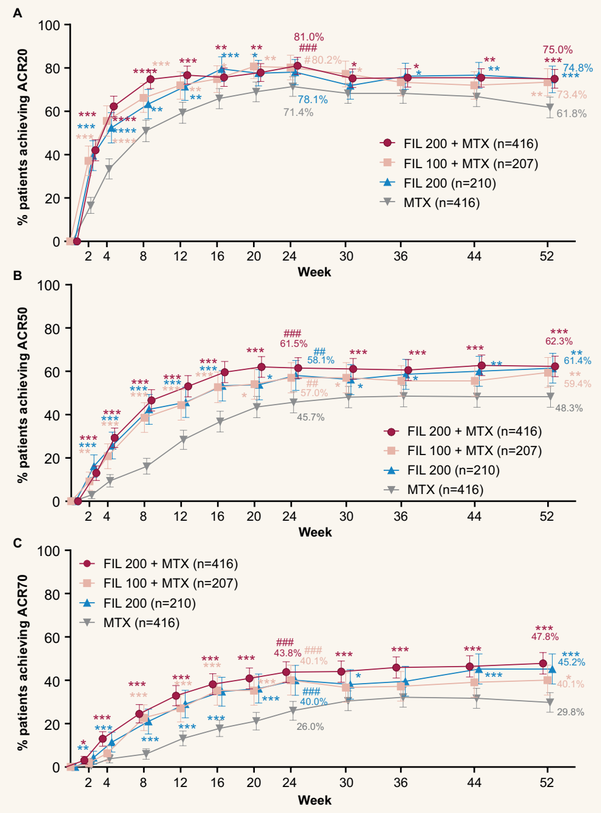
	FIL 200 mg + MTX n=416	FIL 100 mg + MTX n=207	FIL 200 mg n=210	MTX n=416	Total N=1,249
Age, years	53 (13.8)	54 (12.6)	52 (13.9)	53 (13.7)	53 (13.6)
Female, n (%)	325 (78)	158 (76)	166 (79)	312 (75)	961 (77)
RA duration, years	1.9 (3.6)	2.3 (4.7)	2.6 (6.3)	2.3 (5.5)	2.2 (5.0)
Median	0.4	0.4	0.4	0.3	0.4
≤6 months	229 (55)	111 (54)	116 (55)	230 (55)	686 (55)
RF or anti-CCP positive, n (%)	317 (76)	162 (78)	158 (75)	322 (77)	959 (77)
mTSS erosions >0, n (%)	392 (94)	197 (95)	199 (95)	385 (93)	1,173 (94)
DMARD naïve, n (%)	16 (9.8)	16 (9.3)	16 (9.7)	16 (9.4)	16 (8.5)
Prior non-MTX csDMARD use, n (%)	73 (18)	38 (18)	35 (17)	76 (18)	222 (18)
Concurrent oral steroid use, n (%)	143 (34)	88 (43)	89 (42)	174 (42)	494 (40)
Steroid dose, mg/day	6.6 (2.3)	7.2 (2.9)	6.6 (2.2)	6.5 (2.3)	6.6 (2.4)
DAS28(CRP)	5.7 (1.0)	5.7 (1.0)	5.8 (0.9)	5.7 (1.0)	5.7 (1.0)
SJC66	16 (9.8)	16 (9.3)	16 (9.7)	16 (9.4)	16 (9.6)
TJC68	26 (14.5)	25 (13.9)	26 (13.7)	26 (13.8)	26 (14.0)
SGA (VAS)	65 (21.0)	66 (21.6)	68 (19.2)	66 (21.0)	66 (20.8)
PGA (VAS)	66 (17.0)	68 (6.3)	66 (14.4)	67 (16.8)	67 (16.4)
Pain (VAS)	64 (22.0)	67 (22.1)	67 (18.4)	66 (21.4)	65 (21.3)
HAQ-DI	1.5 (0.6)[a]	1.6 (0.7)	1.6 (0.7)	1.6 (0.6)	1.6 (0.6)
hsCRP, mg/L	18.0 (25.3)	17.7 (27.4)	17.3 (23.2)	16.9 (24.4)	17.5 (25.0)
mTSS units[b]	5.7 (1.0)	5.7 (1.0)	5.8 (0.9)	5.7 (1.0)	13.3 (26.7)
CDAI	39.5 (12.8)	39.2 (12.7)	40.0 (12.6)	40.2 (12.5)	39.8 (12.6)

Data are mean (SD), unless otherwise indicated
[a] N=414 for FIL 200 mg + MTX; [b] Campaign A
CCP: cyclic citrullinated peptide; CDAI: Clinical Disease Activity Index; csDMARD: conventional synthetic DMARD; DAS28(CRP): disease activity score with 28 joints and C-reactive protein; DMARD: disease-modifying antirheumatic drug; FIL: filgotinib; HAQ-DI: Health Assessment Questionnaire-Disability Index; hsCRP: high-sensitivity C-reactive protein; mTSS: modified total Sharp/van der Heijde score; MTX: methotrexate; PGA: Physician Global Assessment; RA: rheumatoid arthritis; RF: rheumatoid factor; SD: standard deviation; SGA: Subject Global Assessment; SJC66: swollen joint count of 66; TJC68: tender joint count of 68; VAS: visual analogue scale

ACR responses

- Significantly greater proportions of patients treated with filgotinib vs. MTX achieved ACR20, ACR50 and ACR70 at Week 24, and filgotinib efficacy was sustained through Week 52 (**Figure 3**)
  - For the primary endpoint at Week 24, 81% of patients receiving filgotinib 200 mg + MTX achieved ACR20 vs. 71% with MTX (p<0.001)
- At Week 24, higher proportion of patients achieved ACR50/70 with filgotinib 200 mg monotherapy vs. MTX, though ACR20 response was not significantly higher
- ACR20/50/70 responses were achieved faster with filgotinib vs. MTX; higher rates vs. MTX were achieved at Week 2 for ACR20, ACR50 and ACR70

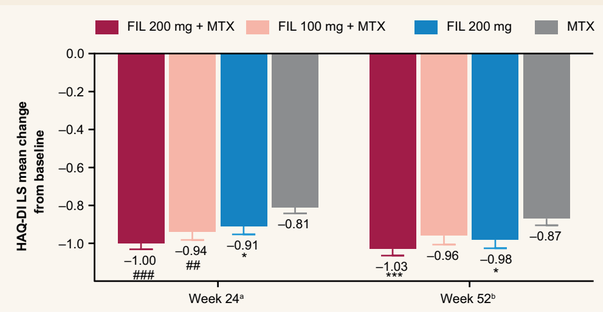
Figure 3. Proportion of patients achieving A) ACR20, B) ACR50, and C) ACR70 through Week 52



Physical function response

- At Week 52, there was greater reduction in HAQ-DI from baseline for patients receiving filgotinib vs. MTX (**Figure 4**)

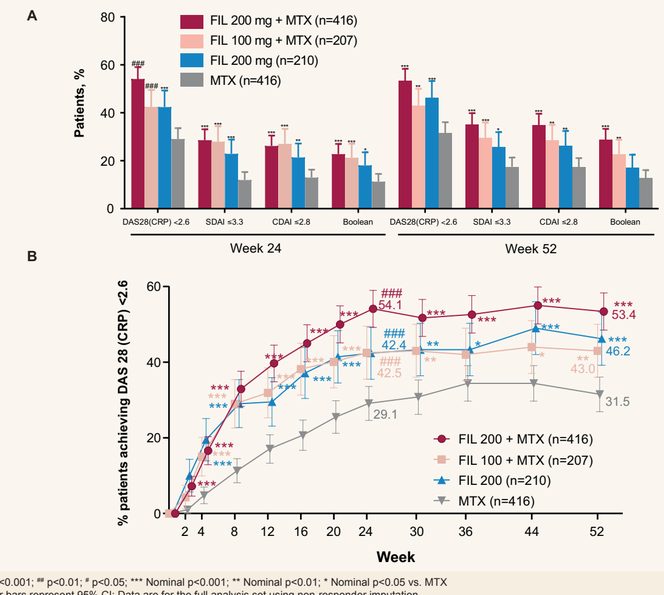
Figure 4. Change in HAQ-DI from baseline



Disease activity states

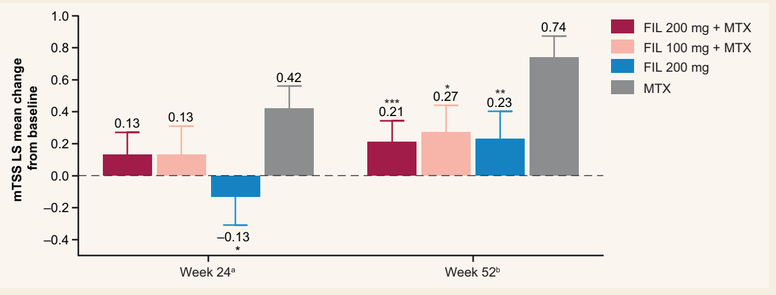
- Rates of DAS28(CRP) <2.6 at Week 24 were 54% for patients receiving filgotinib 200 mg + MTX, 43% for patients receiving filgotinib 100 mg + MTX and 42% for patients receiving filgotinib 200 mg monotherapy vs. 29% for patients receiving MTX and were sustained through Week 52 (**Figure 5**)
- Rates of remission based on CDAI ≤2.8 and Boolean remission criteria were higher in patients receiving filgotinib vs. MTX monotherapy at Week 52 (**Figure 5**)
- Treat-to-target goals were achieved earlier with all filgotinib treatments vs. MTX monotherapy

Figure 5. Proportion of patients with A) DAS28(CRP) <2.6 or remission at Weeks 24 and 52, B) DAS28(CRP) <2.6 over 52 weeks



- There was less radiographic progression as measured by change in mTSS from baseline at Week 52 in patients receiving filgotinib vs. MTX monotherapy (**Figure 6**)
- At Week 52, the odds ratio of change from baseline in mTSS ≤0 vs. MTX was 1.9, 1.5 and 1.5 for filgotinib 200 mg + MTX, filgotinib 100 mg + MTX and filgotinib 200 mg, respectively (**Table 2**)

Figure 6. mTSS change from baseline at Weeks 24 and 52



** Nominal p<0.001; ** Nominal p<0.01; * Nominal p<0.05 vs. MTX
[a] At Week 24, n=355, 184, 173 and 356 patients received FIL 200 mg + MTX, FIL 100 mg + MTX, FIL 200 mg and MTX, respectively
[b] Week 52 n values are not provided due to mTSS change from baseline including both campaign A (through Week 24) and campaign B (through Week 52 including re-reading of baseline and Week 24)
Error bars represent SE; Change from baseline was compared vs. MTX using a mixed-effect model for repeated measures
Week 24 includes only data from campaign A; Week 52 includes data from Campaign A and B
FIL: filgotinib; LS: least squares; mTSS: modified Total Sharp/van der Heijde Score; MTX: methotrexate; SE: standard error

Table 2. Odds of radiographic progression at Week 52

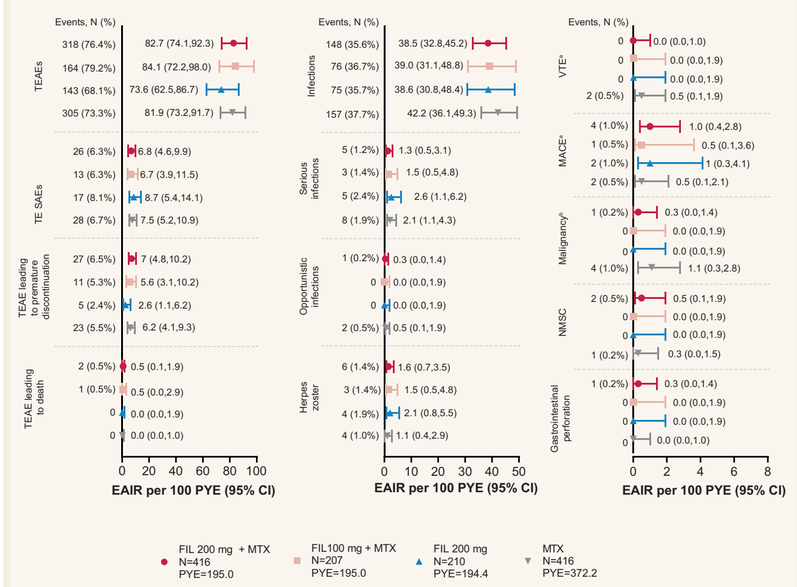
Odds ratio (95% CI) vs. MTX	FIL 200 mg + MTX n=416	FIL 100 mg + MTX n=207	FIL 200 mg n=210
Δ mTSS ≤0.5	2.4 (1.5, 3.9)	1.8 (1.0, 3.0)	1.5 (0.9, 2.6)
Nominal p vs. MTX	<0.001	0.033	0.11
Δ mTSS ≤0	1.9 (1.3, 2.9)	1.5 (1.0, 2.4)	1.5 (0.9, 2.4)
Nominal p vs. MTX	0.001	0.072	0.099

Δ, change; CI: confidence interval; FIL: filgotinib; mTSS: modified total van der Heijde/Sharp score; MTX: methotrexate

Safety

- Overall rates of TEAEs and serious AEs in the filgotinib groups were comparable with MTX (**Figure 7A**)
- Rates of infections and serious infections were similar in patients treated with filgotinib or MTX (**Figure 7B**)
- There were 3 opportunistic infections reported: 1 with filgotinib 200 mg + MTX (oesopogeal candidiasis) and 2 with MTX (cryptococcal pneumonia and Pneumocystis jirovecii pneumonia)
- Overall, herpes zoster rates were low and similar with filgotinib and MTX
- No VTEs occurred in patients receiving filgotinib; 2 adjudicated deep vein thromboses occurred in patients receiving MTX (**Figure 7C**)
- Rates of adjudicated MACE were comparable across treatment groups
- Four deaths occurred; 3 were treatment emergent
  - Causes of death were interstitial pneumonia (filgotinib 200 mg + MTX), lupus myocardiopathy (filgotinib 200 mg + MTX), cerebral and vertebral aneurysms that dissected (filgotinib 100 mg + MTX) and sudden cardiovascular death (68 days after discontinuing filgotinib 200 mg + MTX)

Figure 7. Rates from baseline to Week 52 of A) overall summary TEAEs; B) all, serious, opportunistic and herpes zoster infections; and C) VTE, MACE, malignancies and gastrointestinal perforations



[a] Positively adjudicated; [b] Excluding NMSC
AE: adverse event; CI: confidence interval; EAIR: exposure-adjusted incidence rate; FIL: filgotinib; MACE: major adverse cardiovascular event; MTX: methotrexate; NMSC: non-melanoma skin cancer; PYE: patient-years exposure; TE: treatment-emergent; TEAE: treatment-emergent AE; SAE: serious AE; VTE: venous thromboembolism

- Mean haemoglobin, platelet, neutrophil and lymphocyte counts were within normal range through Week 52. Mean change from baseline at Week 52 were as follows:
  - Haemoglobin increased by 0.5, 0.2, 0.6 and 0.2 g/dL for filgotinib 200 mg + MTX, filgotinib 100 mg + MTX, filgotinib 200 mg and MTX, respectively
  - Platelet count decreased by −32, −21, −44 and −18 x 10^3/µL for filgotinib 200 mg + MTX, filgotinib 100 mg + MTX, filgotinib 200 mg and MTX, respectively
  - Lymphocyte count decreased by −0.27, −0.29, −0.17 and −0.18 x 10^3/µL for filgotinib 200 mg + MTX, filgotinib 100 mg + MTX, filgotinib 200 mg and MTX, respectively
  - Neutrophil count decreased by −1.34, −1.13, −1.06 and −0.76 x 10^3/µL for filgotinib 200 mg + MTX, filgotinib 100 mg + MTX, filgotinib 200 mg and MTX, respectively
- Grade 3 (G3) neutrophil decreases were more frequent in patients receiving filgotinib vs. MTX. G3 lymphocyte decreases were similar among patients receiving filgotinib + MTX and MTX. No G3 lymphocyte decreases were observed with filgotinib monotherapy (**Table 3**)
- G3 alanine aminotransferase elevation was higher in filgotinib + MTX groups than MTX or filgotinib monotherapy, while no difference in G3 aspartate aminotransferase elevation were seen
- No cases of Hy's law were observed
- G3 creatine kinase (CK) elevation incidence was similar with filgotinib vs. MTX, but Grade 4 elevation occurred only with filgotinib. CK elevations were transient and asymptomatic

Table 3. Graded laboratory abnormalities from baseline to Week 52

	FIL 200 mg + MTX n=416	FIL 100 mg + MTX n=207	FIL 200 mg n=210	MTX n=416
Haemoglobin decreased, any grade, n/N (%)	92/413 (22%)	49/204 (24%)	40/207 (19%)	127/412 (31%)
G3	6 (2%)	0	1 (1%)	5 (1%)
G4	NA	NA	NA	NA
Neutrophils decreased, any grade, n/N (%)	73/413 (18%)	27/204 (13%)	29/207 (14%)	40/412 (10%)
G3	2 (1%)	5 (3%)	1 (1%)	1 (<1%)
G4	0	0	1 (1%)	0
Lymphocytes decreased, any grade, n/N (%)	83/413 (20%)	31/204 (15%)	30/207 (15%)	61/412 (15%)
G3	14 (3%)	3 (2%)	0	6 (2%)
G4	0	0	0	0
Platelets decreased, any grade, n/N (%)	24/413 (6%)	11/204 (5%)	8/207 (4%)	16/411 (4%)
G3	1 (<1%)	1 (1%)	0	0
G4	0	1 (1%)	0	1 (<1%)
ALT increased, any grade, n/N (%)	170/413 (41%)	97/204 (48%)	47/207 (23%)	156/413 (38%)
G3	18 (4%)	7 (3%)	1 (1%)	4 (1%)
G4	0	0	0	0
AST increased, any grade, n/N (%)	147/413 (36%)	68/204 (33%)	49/207 (24%)	121/413 (29%)
G3	5 (1%)	3 (2%)	2 (1%)	1 (<1%)
G4	0	0	0	0
Creatinine increased, any grade, n/N (%)	26/413 (6%)	9/204 (4%)	7/207 (3%)	15/413 (4%)
G3	0	0	0	1 (<1%)
G4	0	0	0	0
CPK increased, any grade, n/N (%)	132/413 (32%)	44/204 (22%)	73/207 (35%)	56/413 (14%)
G3	3 (1%)	2 (1%)	2 (1%)	2 (1%)
G4	4 (1%)	1 (1%)	1 (1%)	0

Data are shown as n (%) unless otherwise indicated
ALT: alanine aminotransferase; AST: aspartate aminotransferase; CPK: creatine phosphokinase; FIL: filgotinib; G3: Grade 3; G4: Grade 4; MTX: methotrexate

Conclusions

- Through Week 52, filgotinib 200 mg and 100 mg with MTX, filgotinib 200 mg monotherapy and MTX monotherapy showed sustained efficacy for treatment of RA in MTX-naïve patients based on clinical response, physical function and radiographic progression
  - Although filgotinib 200 mg monotherapy did not achieve statistical significance for ACR20 at Week 24, clinically meaningful improvements were seen compared with MTX for ACR50/70 and remission, along with improvement in physical function and less radiographic progression through Week 52
- Treatment with filgotinib either in combination with MTX or as monotherapy was well tolerated in MTX-naive patients
- No new safety signals were detected. AEs of interest, including rates of infections, serious infections and herpes zoster occurred at similar rates with filgotinib as MTX monotherapy. There were no VTEs reported in the filgotinib treatment groups
- The safety profile of filgotinib in this study is overall consistent with the integrated safety analysis across the Phase 2 and Phase 3 studies in RA[6]

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Disclosures

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