Table 2. Safety outcomes through week 52

Event, n (%)	FIL 200 mg + MTX (n = 416)	FIL 100 mg + MTX (n = 207)	FIL 200 mg (n = 210)	MTX (n = 416)
All AEs	318 (76.4)	164 (79.2)	143 (68.1)	305 (73.3)
Serious AEs	26 (6.3)	13 (6.3)	17 (8.1)	28 (6.7)
Infection	148 (35.6)	76 (36.7)	75 (35.7)	157 (37.7)
Serious infection	5 (1.2)	3 (1.4)	5 (2.4)	8 (1.9)
Herpes zoster	6 (1.4)	3 (1.4)	4 (1.9)	4 (1.0)
VTE	0	0	0	4 (1.0)
MACE (adjudicated)	4 (1.0)	1 (0.5)	2 (1.0)	2 (0.5)
Malignancy ^a	1 (0.2)	0	0	4 (1.0)
NMSC	2 (0.5)	0	0	1 (0.2)
Death	3 (0.7) ^b	1 (0.5) ^c	0	0

^aExcluding NMSC.^b1 lupus cardiomyopathy, 1 atypical interstitial pneumonia, 1 non-treatment-emergent cardiovascular death.^cDissecting cerebral and vertebral aneurysm.

AE, adverse event; FIL, filgotinib; MACE, major adverse cardiovascular event; MTX, methotrexate; NMSC, nonmelanoma skin cancer; VTE, venous thromboembolism.

Conclusion: Efficacy of FIL 200mg + MTX, FIL 100mg + MTX, and FIL 200mg mono was sustained through W52, with faster onset¹ and consistently numerically greater efficacy for FIL 200 vs 100mg. No new safety signals were observed.

Figure. Patients in clinical remission at week 52

***, p < 0.001 vs MTX alone adjusted for multiplicity.

*, p < 0.05; **, p < 0.01; ***, p < 0.001 vs MTX alone; not adjusted for multiplicity.

CDAI, Clinical Disease Activity Index; DAS28(CRP), Disease Activity Score in 28 joints with C-reactive protein; FIL, filgotinib; MTX, methotrexate; SDAI, Simplified Disease Activity Index.

References:[1] Westhovens, et al. *Ann Rheum Dis.* 2019;78(Suppl2):259–60.

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SAT0159

ASSOCIATION BETWEEN JANUS KINASE INHIBITORS AND ALL-CAUSE MORTALITY IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background: According to preliminary analysis of study A3921133, tofacitinib 10mg twice daily was associated with increased occurrence of all-cause mortality and pulmonary embolism compared with anti-tumor necrosis factor (anti-TNF), whereas 5mg tofacitinib twice daily exhibited similar safety profile with anti-TNF.

Objectives: We aim to investigate the role of Janus kinase inhibitors (Jakinibs) in all-cause mortality among RA population via a meta-analysis of RCTs.

Methods: PubMed, Embase and Cochrane Library were systematically searched for RCTs reporting adverse events in RA patients receiving Jakinibs, from inception to October 2018. Absolute risk differences (RD) and 95% confidence interval (CI) were used as an effect measure using the Mantel-Haenszel fixed-effect method.

Results: A total of 31 RCTs randomizing 13,065 patients met the inclusion criteria. During the placebo-controlled phase, there were 16 and 6 deaths in Jakinibs and placebo respectively, accompanied by a numerically higher absolute incidence mortality rate in Jakinibs than in placebo (0.651 vs. 0.531 per 100 patient-years). In direct pairwise comparisons, 2,194 and 2,246 patient-years of exposure in lower and higher Jakinibs reported a total of 19 deaths (10 with lower dose [0.456 per 100 patient-years] and 9 with higher dose [0.401 per 100 patient-years]). Compared with placebo, no significant difference was observed in tofacitinib (RD, 0.01 events/person-year; 95% CI, -0.01 to 0.02; P = 0.52); baricitinib (RD, -0.00 events/person-year; 95% CI, -0.01 to 0.01; P = 0.59); upadacitinib (RD, 0.00 events/person-year; 95% CI, -0.02 to 0.03; P = 0.71); perflitinib (RD, 0.00 events/person-year; 95% CI, -0.05 to 0.06; P = 0.86); decernotinib (RD, 0.02 events/person-year; 95% CI, -0.03 to 0.06; P = 0.44); filgotinib (RD, 0.00 events/person-year; 95% CI, -0.05 to 0.06; P = 0.85). In pairwise comparisons, no dose-dependent impact of Jakinibs on all-cause mortality was not observed in tofacitinib (5mg vs. 10mg, bid), baricitinib (2mg vs. 4mg, qd) upadacitinib (15mg vs. 30mg, qd).

Conclusion: Compared with placebo, there was no significant difference in the all-cause mortality rate observed in patients receiving Jakinibs treatments, but post-marketing data in real-life setting are sorely needed to ascertain their safety in general population.

Large, prospective, well-designed studies are needed to explore the effects of such drugs on diabetes development in the RA patients with high-risk diabetes.

Disclosure of Interests: None declared

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SAT0160

EFFICACY AND SAFETY OF UPADACITINIB IN PATIENTS FROM CHINA, BRAZIL, AND SOUTH KOREA WITH RHEUMATOID ARTHRITIS WHO HAVE HAD INADEQUATE RESPONSE TO CONVENTIONAL SYNTHETIC DISEASE-MODIFYING ANTIRHEUMATIC DRUGS

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Background: Upadacitinib (UPA), an oral, selective JAK-1 inhibitor was effective in global ph 3 trials in rheumatoid arthritis (RA) patients with inadequate response (IR)/intolerance to csDMARDs and bDMARDs.

Objectives: This Phase 3, randomized, double-blind, placebo (PBO)-controlled study assessed the efficacy and safety of UPA in combination with csDMARDs in csDMARD-IR patients with RA from China, Brazil, and South Korea.

Methods: Patients were randomized 1:1 to receive UPA 15mg once daily (QD) or PBO in combination with csDMARDs. The primary endpoint was ACR20 response at Week 12, using non-responder imputation.

Results: 338 patients were randomized, and 310 (91.7%) completed Week 12. At Week 12, statistically significantly more patients receiving UPA vs PBO achieved