Conclusion: In the 16-week EQUATOR trial, the effects of filgotinib on key efficacy endpoints were generally consistent across a range of subgroups based on patient, disease, and treatment characteristics.

References:

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

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THE LONG-TERM EFFECT OF TREATING PSORIATIC ARTHRITIS WITH THE JANUS KINASE 1-SELECTIVE INHIBITOR FILGOTINIB ON LIPID PROFILES: AN ANALYSIS OF THE EQUATOR AND EQUATOR2 TRIALS

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Background: Cardiovascular (CV) comorbidities are common in psoriatic arthritis (PsA); patients are at high risk for major adverse cardiovascular events (MACE).¹ In the Phase 2, double-blind, randomized EQUATOR trial, significant improvements across multiple PsA domains were observed with the oral selective Janus kinase (JAK) 1 inhibitor filgotinib compared with placebo.² Inhibition of JAK signal transducer and activator of transcription signaling is associated with raised serum lipids.³

Objectives: To evaluate the effects of filgotinib on the lipid profile of PsA patients and determine if those with higher MACE risk show similar changes in lipid profile compared with the overall population.

Methods: In EQUATOR, 131 patients with active PsA received filgotinib 200 mg (n=65) or placebo (n=66) once daily for 16 weeks. Patients completing EQUATOR could enter the ongoing EQUATOR2 open-label extension (OLE; NCT03320876), in which patients receive filgotinib 200 mg for up to 148 weeks. Effects of filgotinib on total cholesterol (TC), high-density lipoprotein cholesterol (HDL-C), low-density lipoprotein cholesterol (LDL-C), and TC/HDL-C ratio at OLE Week 52 (68 weeks after EQUATOR initiation) were analyzed. In a post hoc analysis, patients were classified into subgroups according to presence/absence of obesity (baseline body mass index [BMI]; ≥ 30 vs <30 kg/m², respectively), diabetes mellitus, arterial hypertension ($\geq 130/80$ mmHg), hyperlipidemia, and metabolic syndrome. Changes in lipid levels were explored graphically.

Results: 124 patients (95%) completed EQUATOR; 122 (93%) enrolled in the OLE. Of these, 11 patients (9%) discontinued treatment by OLE Week 52. Median (range) exposure to filgotinib was 66.0 (0.4–104.1) weeks. In the OLE, TC, LDL-C, and HDL-C levels increased versus baseline with filgotinib, resulting in a decreased TC/HDL-C ratio. Changes in lipid levels were consistent irrespective of presence of obesity (n=56; **Fig**), diabetes (n=53), arterial hypertension (n=80), hyperlipidemia (n=108), or metabolic syndrome (n=36); baseline lipid values were greater in the higher risk groups. In patients who were assigned placebo in the randomized controlled trial (RCT), HDL-C increased on switching to

filgotinib in the OLE (in a manner similar to that seen in filgotinib-treated patients during the RCT), and remained elevated compared with baseline (**Fig**). Triglyceride levels remained stable throughout, across all subgroups. Seventeen patients (13%) were taking lipid-lowering drugs (LLDs) prior to the start of the trial (and continued to do so); the effect of filgotinib on the lipid profile in these patients was similar to that in the overall population. During the RCT phase, another six patients in the filgotinib group and one in the placebo group began taking LLDs.

Conclusion: In patients exposed to filgotinib for ≥ 52 weeks, the effects on lipid profile were consistent regardless of baseline CV risk. Lipid changes included an elevation in TC and HDL-C, with a decrease in TC/HDL-C ratio.

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Figure 1. Change from baseline in lipid profile in non-obese and obese patients

BL, baseline; BMI, body mass index; FIL, filgotinib; HDL-C, high-density lipoprotein cholesterol; OLE, open-label extension; PBO, placebo; TC, total cholesterol; W, Week

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