remission at week 10 ($p < 0.05$). Higher proportions of patients treated with either dose of FIL than PBO achieved MCS response at week 10. At week 58, higher proportions of bio-naïve and experienced responders, and bio-experienced responders with ≥ 2 biologic or 2 MoA failures treated with maintenance FIL 200 mg than PBO achieved clinical remission ($p < 0.05$). Higher proportions of responders treated with maintenance FIL 200 mg than PBO achieved MCS response at week 58.

Conclusion FIL 200 mg was effective in inducing and maintaining clinical remission in bio-naïve and -experienced patients. Induction results suggest FIL 200 mg is most effective in bio-naïve patients, and those who switch after failure of 1 biologic or MoA.

OMO-3 SAFETY ANALYSIS OF FILGOTINIB FOR ULCERATIVE COLITIS: PHASE 2B/3 SELECTION STUDY AND LONG-TERM EXTENSION RESULTS

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Introduction Filgotinib (FIL) is an oral preferential Janus kinase (JAK) 1 inhibitor. FIL for the treatment of moderately to severely active ulcerative colitis (UC) was evaluated in the phase 2b/3, double-blind, placebo (PBO)-controlled SELECTION study (NCT02914522) and its long-term extension (LTE) study (NCT02914535). Here we report safety results.

Methods Patients received FIL 100 mg, FIL 200 mg or PBO (2:2:1) once daily orally for up to 11 weeks for induction (cohort 1). At week 11, FIL induction responders were rerandomised 2:1 to continue FIL or receive PBO maintenance for 47 weeks (cohort 2). Week 10 non-responders and patients with worsening disease during the maintenance study were eligible for open-label FIL in the LTE. Patients completing the maintenance study could continue blinded dosing in the LTE. Cohort 3 comprised cohorts 1 and 2 and the LTE. Exposure-adjusted incidence rates (EAIRs) and exposure-adjusted event rates (EAERs) per 100 patient-years (PYs) were calculated for treatment-emergent adverse events (AEs).

Results In cohort 1, 1069 patients received FIL and 279 patients received PBO; baseline characteristics were generally similar across treatment groups. EAIRs for AEs of interest were similar across treatment groups in cohorts 1 and 2. Treatment exposure for PBO, FIL 100 mg or FIL 200 mg in cohort 3 (i.e. cohorts 1 + 2 + the LTE) was 318, 360 and 1207 PYs, and median treatment duration was 12, 11 and 67 weeks, respectively. One case of pulmonary embolism occurred with FIL 200 mg induction and three venous thrombosis cases occurred with PBO maintenance/LTE (cohort 3). EAERs for all infections were similar across treatment groups. Opportunistic infections were rare. EAERs for serious infections were low across treatment groups (2.2 [PBO], 3.5 [FIL 100 mg], 2.2 [FIL 200 mg]). EAERs for herpes zoster (HZ) were low in all treatment groups (0.3 [PBO], 0.3 [FIL 100 mg], 1.8 [FIL 200 mg]). HZ infections were cutaneous only and only one was serious. EAIRs for all infections in cohorts 1 and 2 were generally numerically higher for both PBO and FIL in

patients over (vs under) 65 years old and in those with (vs without) biologic treatment failure.

Conclusions FIL was well tolerated in patients with UC. Aggregation of AEs typical for pan-JAK inhibition was not observed, consistent with preferential JAK-1 inhibition with FIL.

OMO-4 DEVELOPING A GENOMIC BIOMARKER OF CANCER RISK IN PATIENTS WITH UC USING UNSELECTED ENDOSCOPIC BIOPSIES

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Introduction Patients with ulcerative colitis (UC) are enrolled into surveillance programs for the early detection of colorectal cancer (CRC). However, most patients under surveillance are low-risk and never progress to CRC, while a significant proportion of CRCs in UC form without a preceding confirmed diagnosis of dysplasia. High resolution chromosomal copy-number alteration (CNA) analysis of unselected formalin-fixed paraffin embedded biopsies taken at surveillance colonoscopies using low pass whole genome sequencing (lpWGS) offers an appealing approach to CRC stratification.

Methods We conducted a retrospective case-control study to compare the CNA burden in four unselected non-neoplastic left-sided colorectal biopsies from patients with E2/E3 UC derived 1-5 years prior to HGD/CRC detection (cases), with that of biopsies from patients who subsequently remained HGD/CRC-free for at least 5 years (controls). The two patient groups were matched by age, gender, duration of IBD and PSC status. lpWGS was performed using a standardised pipeline for epithelial enrichment, DNA extraction, library preparation, next generation sequencing and bioinformatic analysis.

Results 476 biopsies, derived from 42 cases and 77 controls, were analysed. Nearly 80% of patients had a detectable CNA in at least one of their biopsies, with the maximal CNA

Abstract OMO-4 Figure 1