PMO-31 RAPIDITY OF ULCERATIVE COLITIS SYMPTOM IMPROVEMENTS DURING FILGOTINIB INDUCTION: PHASE 2B/3 SELECTION STUDY POST-HOC ANALYSIS

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Introduction Filgotinib (FIL) is a preferential Janus kinase 1 inhibitor. SELECTION was a phase 2b/3 randomised, double-blind, placebo (PBO)-controlled trial to evaluate FIL for the treatment of moderately to severely active ulcerative colitis (UC) (NCT02914522). The aim of this *post hoc* analysis was to assess the speed of improvement in patient-reported outcomes (PROs) during FIL treatment.

Methods Eligible patients who were biologic-naïve or -experienced were enrolled in induction study A or induction study B, respectively. In each study, patients were randomised 2:2:1 to receive FIL 100 mg, FIL 200 mg or PBO once daily orally for 10 weeks. In this *post hoc* analysis, data from daily patient diaries up to day 15 of induction, including Mayo stool frequency subscores (SF; range, 0 [normal] to 3 [≥ 5 stools/day more than normal]) and rectal bleeding subscores (RB; range, 0 [no blood] to 3 [passing blood alone]), were used to evaluate the proportion of patients achieving predefined subscores or subscore reductions.

Results Induction studies A and B comprised 659 and 689 patients, respectively. Baseline characteristics were similar across treatment groups. In induction study A, more patients treated with FIL 200 mg vs PBO reported a reduction in SF of ≥ 1 from baseline as early as day 6 (FIL 200 mg, 35.8%; PBO, 20.6%, $p < 0.01$), and a reduction in RB of ≥ 1 from baseline as early as day 4 (FIL 200 mg, 36.9%; PBO, 23.7%; $p < 0.01$). In induction study B, more patients treated with FIL 200 mg vs PBO reported a reduction in SF of ≥ 1 from baseline as early as day 2 (FIL 200 mg, 21.6%; PBO, 12.1%; $p < 0.05$) and a reduction in RB of ≥ 1 from baseline as early as day 3 (FIL 200 mg, 29.5%; PBO, 17.6%; $p < 0.01$). More patients receiving FIL 200 mg vs PBO achieved the composite score of RB=0 and SF ≤ 1 as early as day 9 in induction study A (FIL 200 mg, 18.8%; PBO, 9.5%, $p < 0.05$) and as early as day 7 in induction study B (FIL 200 mg, 10.7%; PBO, 4.2%, $p < 0.05$).

Conclusions In this *post hoc* analysis of induction study data from SELECTION, improvements in SF and RB were observed within the first week of therapy with FIL 200 mg, compared with PBO. These data demonstrate that FIL 200 mg has rapid onset of action, as assessed by PROs, in both biologic-naïve and biologic-experienced patients with moderately to severely active UC.

PMO-32 PREGNANCY OUTCOMES AFTER STOMA SURGERY FOR IBD: THE RESULTS OF A MULTI-CENTRE RETROSPECTIVE AUDIT

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Introduction There is a paucity of data on pregnancies in women with stomas due to Inflammatory Bowel Disease (IBD) with the existing literature focused on fertility and conception rather than patient experience and outcome of pregnancy after stoma surgery. The aim of this study was to assess stoma, IBD, obstetric and neonatal outcomes in pregnant patients with IBD and a stoma

Methods This was a multi-centre retrospective audit carried out in 15 UK hospitals (11 specialist University Teaching Hospitals and 4 District General hospitals). Female patients who had a confirmed diagnosis of IBD who had experienced pregnancy following stoma formation (ileostomy or colostomy) since 2014 were eligible for inclusion in the study. We excluded patients with stomas for reasons other than IBD and those who had their stoma reversed prior to pregnancy. Pregnancy, stoma and neonatal outcomes were elicited from routinely collected hospital records.

Results Data on 82 pregnancies from 77 patients (mean age 31.4 years, 60.9% Crohn's Disease, 35.4% Ulcerative Colitis, 3.6% IBD-U) were included. Stoma types included Ileostomy in 72 (88%) and colostomy in 10 (12%) women. There was one reported miscarriage, one still birth and 80 live births. Delivery occurred in 58 cases by caesarean section (CS), of which 44 were performed electively and 14 as emergency CS. The overall CS rate was 73%. Premature delivery before week 37 occurred in 19% and birth weight < 2500 g in 17%. Significant stoma related complications occurred during 22 (27%) pregnancies and included stoma prolapse in 9 cases (2 required surgery), parastomal hernias in 3 cases (2 required surgery) and small bowel obstructions in 7 of cases (3 required surgery).

Conclusions To our knowledge this retrospective audit is the only comprehensive modern report of pregnancy outcomes following stoma surgery for Inflammatory Bowel Disease. By examining 82 pregnancies in 77 women, we have shown that women with a stoma due to IBD surgery have higher rates of caesarean section, are more likely to deliver preterm and have low birth weight babies compared to the general population. They also face a significant risk of major stoma complications. This study suggests patients with IBD and a stoma should be counselled appropriately with regards the method of delivery and the potential complications of pregnancy with regards to having a stoma.

PMO-33 INFILIXIMAB BIOSIMILAR SWITCHING – CAN YOU SWITCH MORE THAN ONCE?

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Introduction With the increasing availability of biosimilar infliximab (IFX) products, there is a drive to lower costs without compromising patient outcomes. Switching from originator to biosimilar biologics has been shown to be safe and effective in patients with inflammatory bowel disease (IBD), but less is known about the safety and efficacy of switching between multiple biosimilar brands. The aim of this study was to report the outcomes of patients undergoing a biosimilar IFX switch for the first time (Remsima® to Zessly®) compared to those patients that have undergone a previous originator to