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### P331

#### Final results on efficacy and safety of biosimilar infliximab after one-year: results from a prospective nationwide cohort

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**Background:** Biosimilar infliximab CT-P13 received positive CHMP recommendation in June 2013 for all indications of the originator product. It has been previously shown that CT-P13 is effective and safe in inducing remission in inflammatory bowel diseases (IBD). We report here final results from a prospective nationwide IBD cohort.

**Methods:** A prospective, nationwide, multicentre, observational cohort was designed to examine the efficacy and safety of CT-P13 infliximab biosimilar in the induction and maintenance treatment of Crohn's disease (CD) and ulcerative colitis (UC). Demographic data were collected and a harmonized monitoring strategy was applied. Clinical remission, response and biochemical response was evaluated at week 14, 30 and 54. None of the patients had received infliximab within 12 months prior to initiation of the biosimilar infliximab. Safety data was registered.

**Results:** 353 consecutive IBD (209 CD and 144 UC) patients were included of which 229 patients reached the week 54 endpoint. The age at disease onset was 24/28 years (median, IQR: 19–34 and 22–39) in CD and UC patients, respectively. 31/41% of CD patients had colonic/ileocolonic disease location, 43.5% had complicated disease behaviour, 39% had perianal disease, while 56.2% of UC patients had extensive colitis. 23/19% of patients had received previous anti-TNF therapy in CD and UC, respectively. 60/51% of CD/UC patients received concomitant immunosuppressives at baseline.

49, 53, 48% and 86, 81 and 65% of CD patients reached clinical remission and response by week 14, 30 and 54, respectively. Remission and response rates were 56, 41, 43% and 74, 66 and 50% in UC patients. Previous anti-TNF exposure was associated with decreased clinical efficacy in both CD and UC. Mean CRP decreased significantly both in CD and UC by week 14, which was maintained throughout the 1-year follow-up. 31 (8.8%) patients had infusion reactions, 32 (9%) patients had infections and 1 death occurred.

**Conclusions:** Final results from this prospective nationwide cohort confirm that CT-P13 is effective and safe in inducing and maintaining remission in both CD and UC. Efficacy was influenced by previous anti-TNF exposure, no new safety signals were detected.

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#### Treat to target in Crohn's disease: ultrasonographic response is associated with better outcomes

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**Background:** Crohn's disease (CD) management targets mucosal healing on ileocolonoscopy as a treatment goal. We hypothesized that ultrasonographic response is also associated with better long-term outcomes.

**Methods:** Patients with CD treated with anti TNF agents who had serial small intestine contrast ultrasonography (SICUS) between January 2011 and October 2016 were identified. Disease site (based on bowel wall thickness), extent of lesions, and presence of complications (stenosis, prestenotic dilation, abscess, or fistulas) were evaluated using SICUS. Inclusion required pre-therapy SICUS with follow-up SICUS after 12 months, or 2 SICUS $\geq$ 12 months apart while on maintenance therapy. At second SICUS, complete responders had all improved lesions, non-responders had worsening or new lesions, and partial responders had other scenarios. CD-related outcomes of corticosteroid need, hospitalization, and surgery were assessed at one year from the second SICUS.

**Results:** Seventy CD patients treated with anti-TNF alpha therapy (36% with Infliximab, 64% with Adalimumab) were identified. Most patients had ileal disease (67%) and stricturing phenotype (54%). Based on SICUS, thirty-five patients (50%) were complete sonographic responders, 24 partial (34%), and 11 non-responders (16%). Complete and partial responders at SICUS had a reduced risk for surgery in comparison with non responders [p=0.012 (0.11, CI: 0.021–0.60), p=0.04 (OR 0.17, CI: 0.031–0.93)]. Complete responders at SICUS had a reduced risk for need for rescue corticosteroids in comparison with non responders [p=0.012 (OR 0.17, CI: 0.031–0.93)].

**Conclusions:** Ultrasonographic response to medical therapy is associated with significant reductions in long-term risk of surgery and steroid usage among CD patients. These findings suggest the significance of response assessed by ultrasonography as a treatment target.

### P333

#### Changing patterns of biological therapy use with the introduction of biosimilars in inflammatory bowel disease

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**Background:** Biosimilar infliximab (Inflectra<sup>TM</sup>/Remsima<sup>TM</sup>) has been available in the United Kingdom from 2015. We present data