METHODS: We performed a prospective study of patients with UC from March 2014 to February 2016. If patients have mucosal healing during endoscopy, several biopsy specimens were collected from sigmoid colon and rectum. An expert pathologist evaluated colonic biopsies for histological activity (Geboes score). Histological remission was defined as a Geboes score <3.1. Demographic data, severity data including hemoglobin, hematocrit, white blood cell and platelet counts, albumin, C-reactive protein, and fecal calprotectin (FC) within a week of endoscopy were collected.

RESULTS: Of the 36 patients in histological remission, 9/36 (25%) relapsed after a median follow-up of 29 months (range 2-45 months). FC was significantly higher in patients who relapsed compared with patients who maintained clinical remission (153.7 μg/g vs 103.4 μg/g; p = 0.047). In multivariate analysis, the FC was the only independent predictors of relapse. A receiver operating characteristic analysis estimated a cutoff level of >134.6 μg/g for FC (area under the curve, 0.758 and confidence interval 95%, 0.579–0.937) for predicting relapse during follow-up with 77.8% sensitivity, 74.3% specificity.

CONCLUSION(S): High FC levels can predict relapse in patients with UC. Therefore, regular measurement of FC should be considered in UC patients, even if they have histological remission.

P014

The safety profile of vedolizumab in ulcerative colitis and Crohn’s disease: 4 years of post-marketing data

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BACKGROUND: Vedolizumab is a gut-selective antibody to α4β7 integrin approved for the treatment of moderate-to-severe UC and Crohn’s disease in adults. The safety and efficacy of vedolizumab have been demonstrated in 3 phase 3, randomized trials (NCT00783718, NCT00783692, and NCT01224171), but these only included patients meeting eligibility criteria, who may not reflect real-world clinical practice. Here, we describe the first 4 years of post-marketing safety data reported to Takeda Pharmaceutical Company Ltd (Takeda).

METHODS: The Vedolizumab Global Safety Database contains all adverse event (AE) reports received by Takeda since vedolizumab was approved on 20 May 2014. Reports received between approval and 19 May 2018 were identified using Medical Dictionary for Regulatory Activities Version 21.1. The vedolizumab exposure was calculated based on the number of vials shipped globally, assuming 8-week dosing intervals.

RESULTS: In approximately 208,050 patient-years of vedolizumab exposure, 80,218 AEs were reported in 32,752 patients. Of these AEs, 37,662 (47%) and 34,259 (43%) were in patients with CD and UC, respectively, while 8,297 (10%) were in individuals receiving vedolizumab for other indications (off-label use) or without a reported indication. Gastrointestinal AEs were the most common type reported in patients with CD (6,156 [16%]) and UC (5,703 [17%]). There were 5,230 (14%) serious AEs in patients with CD and 3,380 (10%) in patients with UC, most commonly related to exacerbation of underlying disease (CD, 496 patients [8%] and UC, 411 [10%]). Infusion-site reactions were reported in 211 patients (CD, 109; UC, 102). Malignancies were reported in 140 patients with CD and 123 with UC; those most commonly reported were lower gastrointestinal (23 patients [16%] and 34 [27%], respectively). Hepatobiliary AEs were reported in 152 patients with CD and 177 with UC. Infections were reported in 2,064 patients with CD and 2,812 with UC of these, 710 (28%) and 427 (15%), respectively, were serious. Opportunistic infections were reported in 95 patients with CD and 193 with UC, including one case of progressive multifocal leukoencephalopathy in a patient with CD and untreated HIV receiving long-term immunosuppressant treatment using other infections. AEs of particular clinical significance were reported in low numbers, with nocardiosis and histoplasmosis reported in 2 and 9 patients with CD, respectively, and tuberculosis reported in 5 patients with CD and 4 with UC. Of the 652 pregnancy-related reports, 46% had an associated AE; the most common was spontaneous abortion (48 reports). There were 10 reported congenital abnormalities. Of the patients with CD or UC reporting AEs, 74% continued vedolizumab treatment.

CONCLUSION(S): These data suggest that the favorable safety profile of vedolizumab in CD and UC in the post-marketing setting is consistent with that established in clinical trials. Limitations of post-marketing safety reports, including incomplete data, voluntary reporting, increased reporting of serious vs non-serious AEs and difficulty establishing a causal relationship between drug and event, must be considered when interpreting these results. Most reported AEs with vedolizumab were non-serious, and frequencies of AEs of particular clinical interest appeared low.

P015

Quantification of inflammatory bowel disease symptom burden based on patient preferences

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BACKGROUND: Inflammatory bowel diseases (IBD) cause a wide variety of gastrointestinal symptoms including abdominal pain, diarrhoea, and rectal bleeding. It is well known that the type and level of symptoms that patients experience varies widely. In previously presented work, our group performed a series of focus groups to understand the impact of different symptoms on patients. We
identified that symptoms that cause disability, anxiety, and those that are out of the patient’s control are perceived to be the most burdensome. The 4 gastrointestinal symptoms that patients described as most burdensome were abdominal pain, rectal bleeding, urgency, and incontinence, and stool frequency. Additionally, we observed that the relative burden of different symptoms varied. Therefore, the aim of the current study is to quantify the relative importance of 4 common IBD symptoms and their severity for IBD patients.

**METHODS:** To quantify the relative importance of different symptoms and severity levels, a choice-based conjoint (CBC) analysis survey was developed. In the survey, patients are asked to complete CBC questions, in which they choose one out of 2 scenarios with different levels of severity for 4 different symptoms. Abdominal pain, rectal bleeding, stool frequency, and urgency/incontinence are the 4 symptoms included in the survey. Severity levels are based on the levels used in common disease activity measures. Clinical information including the type of IBD and disease duration is obtained from the survey. Hierarchical Bayes analysis is used to quantify the relative importance of different severity levels for each of the symptoms. Patients 18 years or older with a confirmed IBD diagnosis are eligible to participate. Patients with a stoma are excluded.

**RESULTS:** Thus far, 108 eligible patients have completed the survey (46% male, mean age 59 [SD 15]). Two patients were excluded after finishing the survey as they did not fulfill eligibility criteria (stoma and unconﬁrmed IBD diagnosis). Four eligible patients started but did not finish the survey. Of the included patients, 55% were diagnosed with CD, 39% with UC, and 6% with IBDU, with an average disease duration of 9 years (SD 7). Conjoint analysis revealed that urgency/incontinence was the most important symptom for patients: 1.5x more important than abdominal pain, 2.2x more important than rectal bleeding, and 3.5x more important than stool frequency. As expected, higher symptom levels were perceived to be more important than lower symptom levels. In particular, urgency leading to incontinence was a major factor driving patients decisions to select one scenario over another.

**CONCLUSION(S):** In this study, we quantified the relative importance of 4 common symptoms and severity levels that IBD patients experience. We found large differences in the observed importance of different symptoms for IBD patients. Urgency/incontinence was shown to be particularly bothersome, while stool frequency by itself was not perceived to be very burdensome. These results will be used to develop a score to quantify symptom burden in IBD patients.

**P017**

Cost burden of CD and UC is significantly higher up to 10 years before diagnosis: A Danish register-based study

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**BACKGROUND:** Several genetic, bacterial, and environmental factors appear to lead to the onset of ulcerative colitis (UC). Moreover, UC seems to be associated with alterations in lipid metabolism, and the majority of significant concentration differences in the observed importance of different symptoms and severity levels for IBD patients. Urgency/incontinence was shown to be particularly bothersome, while stool frequency by itself was not perceived to be very burdensome. These results will be used to develop a score to quantify symptom burden in IBD patients.

**METHODS:** Lipidomics in ulcerative colitis reveal disruption of mucosal lipid composition associated with the disease state

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**BACKGROUND:** Ulcerative colitis (UC) is a chronic inflammatory bowel disease (IBD) characterized by inflammation of the rectum and colon without transmural involvement. It is associated with alterations in lipid metabolism, and the majority of significant concentration differences in the observed importance of different symptoms and severity levels for IBD patients. Urgency/incontinence was shown to be particularly bothersome, while stool frequency by itself was not perceived to be very burdensome. These results will be used to develop a score to quantify symptom burden in IBD patients.

**METHODS:** Lipidomics in UC revealed alterations in the mucosal lipid composition. In this study, we aimed to characterize mucosal lipid proﬁles in UC patients in the year before diagnosis. CD/UC patients had signiﬁcantly more healthy contacts than controls prior to inﬂammatory bowel disease (IBD) diagnosis, with 51.6% of CD patients and 52.4% of UC patients having other diagnoses related to the digestive system. The average attributable costs were higher the ﬁrst year after diagnosis, equaling €1,377 per CD patient and €2,960 per UC patient. Hospital admission costs accounted for 36% for CD and 31% for UC patients—prescription medicine for 3% and 7%, respectively. 

**CONCLUSION(S):** This study provides population-based evidence of the substantial economic burden of CD and UC 10 years prior to and 5 years after diagnosis. These ﬁndings may indicate a significant diagnostic delay of CD and UC and warrants more research into the possible causes.