Published literature have previously demonstrated that the gut microbiota in healthy South Asians living in the subcontinent was enriched with populations of *Lactobacillus*, *Ruminococcus*, and *Bifidobacterium* bacteria. In our South Asian IBD cohort these microbial communities were significantly reduced.

**Conclusion** This is the first study to date investigating the gut microbial composition in the migrant population with IBD in UK. The gut microbiota in South Asian IBD patients is similar to Caucasian IBD patients living in UK. Our findings suggest the need to explore further the role environmental factors in the development of IBD associated dysbiosis but also the role of host factors in pathogenesis.

**ADTU-06 ‘REAL WORLD’ OUTCOMES OF VEDOLIZUMAB OVER 12 MONTHS: THE CROSS PENNINE MULTICENTRE EXPERIENCE**

1Christian Selinger*, 2Scott Levison, 3Elena Eliadou, 2Robert Willett, 2Anna Carter, 2Karen Kemp, 2Catherine Stansfield, 3Arash Assadsangabi, 2Karen Kemp, 3Catherine Stansfield, 3Arash Assadsangabi, 4Sreedhar Subramaniam, 4Chris Probert, 5Paul Smith, 2Eleanor Liu, 2Simon Lunt, 2John Hamlin, 2Marco Lenti, 2Leeds Teaching Hospitals NHS Trust, Leeds, UK; 3Central Manchester University Hospitals, Manchester, UK; 5Royal Liverpool and Broadgreen University Hospitals, Liverpool, UK; 2Salford Royal Hospitals, Salford, UK; 2Bolton NHS Trust, Bolton, UK; 4Bradford Teaching Hospitals, Bradford, UK; 4Royal Liverpool and Broadgreen University Hospitals, Liverpool, UK; 2Wrightington, Wigan and Leigh NHS Trust, Wigan, UK; 2The Pennine Acute Hospitals NHS Trust, Manchester, UK

**Background** Vedolizumab (VDZ) is a gut selective α4β7 anti-integrin approved for the treatment of UC and CD. We aimed to assess one year clinical and safety outcomes of VDZ.

**Methods** We previously reported 12 week outcomes using retrospectively collected demographic, clinical, and adverse effects data of patients treated with VDZ at 8 UK centres since 2014. We now report longer term outcomes, evaluating clinical response at week 12 and 52, using Physician Global Assessment, Harvey Bradshaw Index (HBI) and partial Mayo Score (pMS).

**Results** Of 203 patients, 135 had CD (96% anti-TNF experienced), and 68 UC (66% anti-TNF experienced). 101 received concomitant immunomodulator therapy and 97 received steroid bridging therapy.

Of 135 CD patients, 9 discontinued VDZ prior to week 12. At week 12, 38.5% were in PGA remission and 40.0% had a PGA response. Between week 12 and 52, a further 35 patients discontinued VDZ. At week 52 PGA remission and response were seen in 39.2% and 24.3% respectively. Mean pMS decreased from 9.2 (baseline) to 5.1 (week 12) and 5.2 at week 52 (p<0.01).

Of 68 UC patients, 3 discontinued VDZ prior to week 12. At week 12, 48.5% were in PGA remission and 42.6% had a PGA response. Between week 12 and 52, a further 9 patients discontinued VDZ. At week 52, PGA remission and response were seen in 67.2% and 16.4% respectively. Mean pMS decreased from 6.1 (baseline) to 3.1 (week 12) and 2.2 (week 52; p<0.01).

Adverse events were reported in 48 cases (24%). Of these 29 were infection related. Overall incidence of infection was 11.1 per 100 person-years of VDZ exposure.

**Conclusion** In our cohort of refractory (predominantly anti-TNF experienced) patients, VDZ proved to be safe and effective. Although at 12 weeks response/remission rates were similar in CD and UC, VDZ appeared to be more effective at maintaining remission for UC compared to CD. The incidence of infectious complications was lower than that seen with anti-TNF therapies (average 14 per 100 person-years).

**PTU-001 TOFACITINIB, AN ORAL JAK INHIBITOR, IN THE TREATMENT OF UC: OPEN-LABEL, LONG-TERM EXTENSION STUDY**

1Stuart Bloom*, 2Gary R Lichterstein, 3Edward V Loftus, 2Nevin Lavenda, 2Gary S Friedman, 2Haiying Zhang, 2Venjin Wang, 2Andrew J Thorpe, 2Chudy I Ndulueka, 2Chinyu Su. 1Ucl Hospital Bhs Foundation Trust, London, UK; 2School of Medicine of the University of Pennsylvania, Philadelphia, USA; 3Mayo Clinic, Rochester, USA; 4Pfizer Inc, Collegeville, USA

**Introduction** Tofacitinib is an oral, small molecule JAK inhibitor that is being investigated for ulcerative colitis (UC). The efficacy and safety of tofacitinib was demonstrated as induction and maintenance therapy in 3 Phase 3, randomised, placebo-controlled studies (OCTAVE Induction 1, NCT01465763; OCTAVE Induction 2, NCT01458951; OCTAVE Sustain, NCT01458874) in patients (pts) with moderate to severe UC.

**Methods** We present interim safety and efficacy data up to 3 years of treatment (as of 8 July 2016) from an ongoing Phase 3, multicentre, open-label, long-term extension study (OLE; NCT01458574) in patients (pts) with moderate to severe UC. The efficacy and safety of tofacitinib was demonstrated as induction therapy in OCTAVE Induction 1 or 2. Pts in remission at Week 52 of OCTAVE Sustain received tofacitinib 5 mg twice daily (BID); all others received 10 mg BID. At Month 2, all pts underwent endoscopy, and non-responders from Induction were mandated to withdraw if no evidence of clinical response was shown. Remission was defined by a Mayo score ≤2 with no individual subscore >1, and rectal bleeding subscore of 0. Binary efficacy endpoints were derived from Mayo score, based on local-read endoscopic subscore.

**Results** Of 135 pts who had completed or demonstrated treatment failure in OCTAVE Sustain, or who were non-responders after completing OCTAVE Induction 1 or 2, 5 mg and 10 mg BID, respectively. Malignancies excl. NMSC were reported in 9 (1.2%) pts with 5 and 10 mg BID. At Month 2, all pts underwent endoscopy, and non-responders from Induction were mandated to withdraw if no evidence of clinical response was shown. Remission was defined by a Mayo score ≤2 with no individual subscore >1, and rectal bleeding subscore of 0. Binary efficacy endpoints were derived from Mayo score, based on local-read endoscopic subscore.

**Conclusions** Efficacy results from this OLE study support sustained efficacy with tofacitinib 5 and 10 mg BID.

Funded by Pfizer Inc.