PTU-002 ACHIEVING BIOCHEMICAL REMISSION IN CROHN’S DISEASE WITH ADALUMAB THERAPY UTILISING THERAPEUTIC DRUG MONITORING

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Introduction Adalimumab (ADA) is a well-established treatment for Crohn’s disease (CD). Despite this limited data are available regarding the relationship of serum ADA levels, and antibodies to ADA (ATA) with clinical outcomes. Methods We performed a prospective cross-sectional study to investigate the association of serum ADA and ATA levels and clinical outcomes. Inclusion criteria were a diagnosis of CD currently in Phase III development for the treatment of ulcerative colitis and Crohn’s disease (CD). In a Phase II study in patients with moderately to severely active CD (FITZROY, ClinicalTrial.gov ID#NCT02048618), 10 weeks of treatment with FIL 200 mg once daily demonstrated significantly higher clinical remission rates compared with placebo. Here, we report treatment-induced changes in serum cytokines, C-reactive protein (CRP) and faecal calprotectin (FC) and investigation of the association of these biomarkers with endoscopic improvement.

Methods Serum samples were acquired at baseline (BL), and Weeks 2, 4, and 10 and stool samples collected at BL and Weeks 2, 4, and 10. Serum cytokines were measured by chemiluminescence, CRP by immunoturbidimetry and FC by Calprest®. Percent change of biomarkers from BL at post-treatment visits were compared between placebo (PBO) (n=44) and FIL-treated (n=128) patients using an ANCOVA model adjusting for BL biomarker levels and stratification factors (steroid use, prior anti-TNF exposure and BL CRP). Association of% change in biomarkers with Week 10 endoscopic response (50% decrease from BL in SES-CD score) was assessed by AUROC.

Results Biomarker levels at BL were comparable between PBO and FIL treatment groups, except IL-17A and VEGF-A which were higher in PBO (medians at 3.2 and 547.2 pg/ml) vs. FIL (2017;376:1723–36).

PTU-003 FULGITINIB DECREASES INFLAMMATORY MARKERS ASSOCIATED WITH ENDOSCOPIC IMPROVEMENT IN MODERATE TO SEVERE ACTIVE CROHN’S DISEASE

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Introduction Fulgitinib (FIL) is a JAK1-selective inhibitor currently in Phase III development for the treatment of ulcerative colitis and Crohn’s disease (CD). In a Phase II study in patients with moderately to severely active CD (FITZROY, ClinicalTrial.gov ID#NCT02048618), 10 weeks of treatment with FIL 200 mg once daily demonstrated significantly higher clinical remission rates compared with placebo. Here, we report treatment-induced changes in serum cytokines, C-reactive protein (CRP) and faecal calprotectin (FC) and investigation of the association of these biomarkers with endoscopic improvement.