for 30 weeks (treatment period 1). The primary endpoint was a ≥20% improvement in ACR response (ACR20) at Wk 14. At Wk 30 (treatment period 2 [TP2]), patients receiving IFX-EU were blindly re-randomised (1:1) to remain on IFX-EU or transition to GP1111 for 24 wks. Here we report longer-term efficacy, safety and immunogenicity data from Wks 30–54.

Results: 850 patients were randomised initially (GP1111, n=324; IFX-EU, n=326). At Wk 30, 556 patients entered TP2 (continued GP1111, n=280; continued IFX-EU, n=143; switched from IFX-EU to GP1111, n=143). ACR20 rates and DAS28-CRP scores were comparable between groups at all TP2 visits after randomisation in the TP2 population (figure 1). Incidences of TP2 treatment-emergent adverse events (AEs) (36.6%, 33.6%, and 37.8%), serious AEs (4.6%, 7.7% and 2.8%) and infusion-related reactions (3.2%, 8.4% and 4.2%) were comparable between the GP1111/IFX-EU, IFX-EU/GP1111, and IFX-EU/IFX-EU111 groups, respectively. Pre-dose ADA rates at Wk 30 (TP2) were 47.1%, 53.8% and 45.5% for the GP1111/IFX-EU, IFX-EU/GP1111, and IFX-EU/IFX-EU111 groups, respectively. Overall, post-dose ADA rates in TP2 were comparable between groups (52.1%, 60.1%, and 58.0% respectively).

Abstract FR0137 – Figure 1. ACR20 response rate and change in DAS28-CRP score at Wk 30 and 54 for the overall population during TP2

Conclusions: Results from TP2 (Wks 30–54) continued to show the absence of clinically meaningful differences in efficacy, safety and immunogenicity between patients with RA remaining on GP1111 or IFX-EU, or when blindly switched from IFX-EU to GP1111.