Background: Sandoz etanercept (SDZ ETN) is a biosimilar of etanercept (ETN). COMPACT is an ongoing, non-interventional study, evaluating the effectiveness, safety, and quality of life with SDZ ETN treatment in patients (pts) with rheumatoid arthritis (RA), axial spondyloarthritis (axSpA) or psoriatic arthritis (PsA) in real-world conditions.

Objectives: We have reported an interim analysis, with the effectiveness and safety data focusing on pts who were in clinical remission or low disease activity under treatment with reference ETN or biosimilar ETN other than SDZ ETN (initial ETN; iETN) and switched to SDZ ETN.

Methods: Pts aged ≥18 years for whom treatment with SDZ ETN were initiated are being enrolled. Pts were categorized under four treatment groups based on prior treatment status: Group A, pts on clinical remission or low disease activity under treatment with iETN and switched to SDZ ETN; Group B, pts who received targeted therapies and switched to SDZ ETN; Group C, biologic naïve considered uncontrolled with conventional therapy; Group D, DMARD naïve with recent diagnosis of RA considered suitable for treatment initiation with a biologic and started under treatment with iETN or biosimilar ETN other than SDZ ETN (initial ETN; iETN) and switched to SDZ ETN.

Results: Of the 1437 pts recruited (analysis cut-off date: 16 Oct, 2020), 567 pts were switched from iETN, 163 were switched from other targeted therapies, 697 were biologic naïve, and 10 were RA DMARD naïve. Among pts who switched from iETN, 51.5% had RA, followed by axSpA (28.0%) and PsA (20.5%). Comorbidities were more frequent in pts with RA (70.2%) followed by PsA (58.6%) and axSpA (49.7%). At BL, whilst receiving iETN, the mean (SD) DAS28-ESR scores were 2.5 (1.1) and 2.1 (1.1) in pts with RA and PsA, respectively (figure 1). The mean change from BL in DAS28-ESR score at Week 24 after switch to SDZ ETN was -0.1 (1.0) and 0.0 (1.0) in pts with RA and PsA, respectively. In pts with axSpA, the mean (SD) ASDAS score was 1.5 (0.7) at BL, mean change from BL in ASDAS score at Week 24 was 0.1 (0.5). At BL, the mean (SD) HAQ-DI scores were 0.8 (0.7), 0.5 (0.7) and 0.5 (0.6) in pts with RA, PsA and axSpA, respectively. Overall, the proportion of patients with at least one adverse event (AE) was 37.3%, 33.6% and 25.8% in pts with RA, PsA and axSpA, respectively. Serious AEs were reported in 6.5%, 1.7% and 3.1% of pts with RA, PsA, and axSpA, respectively. Injections site reactions were reported in 2.7%, 0.9% and 1.3% of pts with RA, PsA and axSpA, respectively.

Conclusion: The interim interim analysis results shows that switch from iETN to SDZ ETN does not impact the effectiveness of ETN in pts with RA, axSpA or PsA, without any new safety signals.

Disclosure of Interests: Marc Schmalzing Speakers bureau: Novartis, AbbVie, Chugai/Roche, Janssen-Cilag, Lilly, Consultant of: Astra-Zeneca, Chugai/Roche, Hexal/Sandoz, Gilead, AbbVie, Janssen-Cilag, Boehringer/Ingelheim, Grant/research support from: Travel grants; Chugai/Roche, Boehringer/Ingelheim, Celgene, Medac, Ayman Askari: None declared, Tom Sheeran Speakers bureau: Pfizer, UCRO, Roche, Consultant of: Novartis, Pfizer, Grant/research support from: Novartis, UCRO, Roche, David Walsh: None declared, Javier de Toro Santos: None declared, JULIO CESAR VAZQUEZ PEREZ-COLEMAN Speakers bureau: Sandoz, Abbvie, Sanofi, Fresenius, Charlotte Both Employee of: Sandoz employee Global Medical Affairs, Fabrizio Furlan Employee of: Sandoz employee Global Medical Affairs, Sohaib HACHAICHI Employee of: Sandoz employee Global Medical Affairs, Herbert Kellner: None declared.

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Figure 1. Disease activity in patients who switched from iETN to SDZ ETN.