csDMARD therapy but had comparable improvements in PROs at 6 months from initiation.

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FRI0189 SIMILAR EFFICACY AND SAFETY OF BIOSIMILAR CANDIDATE BI 695501 AND ADALIMUMAB ORIGINATOR REFERENCE PRODUCT IN PATIENTS WITH MODERATE TO SEVERE ACTIVE RHEUMATOID ARTHRITIS: 24 WEEK RESULTS FROM A PHASE III CLINICAL STUDY (VOLTAIRE®-RA)

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Background: PK bioequivalence of BI 695501, a biosimilar candidate, and the adalimumab originator was demonstrated previously (VOLTAIRE®-PK: Wynne et al., Expert Opin Investig Drugs 2016;25:1361–70) and led to further clinical development.

Objectives: To demonstrate clinical equivalence of BI 695501 with the adalimumab originator by comparing efficacy, safety and immunogenicity using a clinical model sensitive to detect potential differences between the two biologics.

Methods: In this 58-week, multi-national, multicentre, randomised, double-blind, parallel arm Phase III study (NCT02137226), 645 pts (18–80 years) with moderate to severe active RA on stable treatment with methotrexate were randomised to receive US-licensed SC adalimumab originator or BI 695501 40mg Q2W for 24 weeks. At Wk 24, pts on adalimumab originator were re-randomised to continue the adalimumab originator or switch to BI 695501 until Wk 48. Pts on BI 695501 were dummy re-randomised. Co-primary end points were proportion of pts achieving ACR20 at Wks 12 and 24. Equivalence between BI 695501 and the adalimumab originator was demonstrated if the relevant confidence intervals (CI) for differences in ACR20 response rate at Wks 12 and 24 were within the predefined margins (Wk 12: 90% CI –12%, 15%; Wk 24: 95% CI –15%, 15%). The secondary efficacy end point was change from baseline in DAS28-ESR at Wks 12 and 24. Safety and immunogenicity were exploratory objectives. Wk 48/58 data will be reported later.

Results: The co-primary end points of ACR20 response at Wks 12 and 24 were within the pre-defined criteria for equivalence, demonstrating clinical equivalence between BI 695501 and the adalimumab originator (Table 1).

The proportion of pts with treatment-emergent adverse events (TEAE) was similar between the BI 695501 and the adalimumab originator treatment groups (Table 2).

Table 1. Response at Weeks 12 and 24

ACR, %	Week 12		Week 24	
	BI 695501 n=321	Adalimumab originator n=318	BI 695501 n=321	Adalimumab originator n=318
ACR20*	67.0	61.1	69.0	64.5
ACR50	29.3	31.0	36.8	36.8
ACR70	10.1	11.1	13.6	18.2
DAS28-ESR [†] , mean change from baseline (95% CI)	–2.1 (–2.28, –2.01)	–2.0 (–2.18, –1.91)	–2.4 (–2.51, –2.21)	–2.4 (–2.54, –2.24)

*Week 12 risk difference (RD) and 90% CI for BI 695501-adalimumab originator are 5.9% and 90% CI (–0.9%, 12.7%); [†]Week 24: RD and 95% CI are 4.5% and (–3.4%, 12.5%).

Table 2. Overview of TEAEs up to Week 24

Pts, n (%)	BI 695501 (n=324)	Adalimumab originator (n=321)
≥1 TEAE	138 (42.6)	148 (46.1)
≥1 TEAE related to trial drug	36 (11.1)	44 (13.7)
≥1 Non-serious TEAE	135 (41.7)	141 (43.9)
≥1 serious TEAE	12 (3.7)	18 (5.6)
≥1 serious TEAE related to trial drug	1 (0.3)	5 (1.6)
A TEAE leading to trial drug discontinuation	8 (2.5)	11 (3.4)
A TEAE leading to death	0 (0.0)	0 (0.0)

Rates of serious AEs and discontinuation due to TEAEs were similar across the groups. No deaths were reported during the study. Similar frequencies of pts tested positive for anti-drug antibodies (BI 695501 43.2%; adalimumab originator 47.8%), and neutralising antibodies (BI 695501 16.0%; adalimumab originator 20.6%) in both groups at Week 24.

Conclusions: This study in pts with RA demonstrated that BI 695501 and the adalimumab originator are highly similar in terms of efficacy, safety and immunogenicity.

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FRI0190 CLINICAL OUTCOMES FROM A NATIONWIDE NON-MEDICAL SWITCH FROM ORIGINATOR TO BIOSIMILAR ETANERCEPT IN PATIENTS WITH INFLAMMATORY ARTHRITIS AFTER 5 MONTHS FOLLOW-UP. RESULTS FROM THE DANBIO REGISTRY

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Background: In Denmark, biological drugs are provided free by the hospitals to the patients via a tax-based system. In 2015 a non-medical switch from originator infliximab to CT-P13 was conducted (1). According to national guidelines in April 2016, a non-medical switch from originator (ETA, Enbrel® 50 mg/week) to biosimilar etanercept (SB4, Benepal®) was dictated when SB4 was marketed, including patients with inflammatory rheumatic diseases treated in routine care.

Objectives: To investigate 3 months' disease activity and 5 months' treatment withdrawal in ETA-treated patients (pts) with rheumatoid arthritis (RA), psoriatic arthritis (PsA) and axial spondyloarthritis (SpA), who were switched to SB4 and monitored prospectively in the DANBIO registry.

Methods: Pts with RA/PsA/SpA followed in DANBIO since start of first bDMARD were included. Disease activity at 3 months before switch (pre-switch), at the switch and after 3 months (post-switch) and changes over time (Δ pre-switch and Δ post-switch) were calculated. Disease flare was defined as Δ DAS28 $\geq$ 1.2 (RA/PsA) or Δ ASDAS $\geq$ 1.3 (SpA). Factors associated with withdrawal (gender/age/diagnosis/bDMARD-treatment-no/comedication methotrexate/baseline CRP/patient's global score) were explored by multivariable Cox regression analysis.

Results: In total, 1548 switch pts were identified (891 RA, 335 PsA, 322 SpA). 60% were women, age (median (IQR) 56 (44–65) yrs). Prior ETA treatment duration was 5.2 (3.2–8.0) yrs. ETA was the first biological treatment in 49%, and the second in 33% of pts. Concomitant MTX was given in 60% (RA)/49% (PsA)/15% (SpA). Median follow-up time was 154 (110–178) days. Disease activity remained largely unchanged 3 months prior to vs. after the switch (Table). The proportion of patients with disease flare pre-/post switch was 8%/13% (RA), 9%/13% (PsA), 5%/5% (SpA).

Overall, 129 pts (9%) stopped SB4 treatment during 5 months' follow-up (Table). Prior ETA treatment duration in these patients was 4.5 (2.7–7.1) years.

Higher patient's global score (HR 1.12/cm, 95% CI (1.05–1.21), p=0.002) and no concomitant methotrexate (HR 2.28 (1.48–3.52), p<0.001) at baseline were associated with withdrawal.

Table Disease activity 3 months pre/post-switch and changes in patients switched from originator to biosimilar etanercept. Reasons for withdrawal after 5 months' follow-up are also shown

	Disease activity, median(IQR)			Changes, median(IQR)		P*
	pre-switch	switch	post-switch	Δ pre-switch	Δ post-switch	
RA, n=891						
DAS28	2.1 (1.7-2.9)	2.1 (1.6-2.9)	2.2 (1.6-3.1)	0.0 (-0.4-0.5)	0.0 (-0.4-0.5)	0.2
HAQ	0.6 (0.2-1.3)	0.8 (0.1-1.3)	0.8 (0.3-1.3)	0.0 (-0.1-0.1)	0.0 (-0.1-0.1)	0.7
CRP, mg/l	3 (1-7)	2 (1-6)	3 (1-6)	0 (-2-1)	0 (-1-1)	0.02
VAS global, mm	30 (13-57)	28 (13-55)	31 (11-62)	0 (-11-9)	0 (-9-11)	0.1
PsA, n=335						
DAS28	2.0 (1.5-2.6)	2.0 (1.6-2.8)	2.1 (1.5-3.0)	0.0 (-0.2-0.5)	0.0 (-0.6-0.5)	0.7
HAQ	0.5 (0.1-1.1)	0.5 (0.0-1.1)	0.5 (0.1-1.1)	0.0 (-0.1-0.1)	0.0 (-0.1-0.1)	0.7
CRP, mg/l	2 (1-4)	2 (1-4)	2 (1-4)	0 (-2-1)	0 (-1-1)	0.04
VAS global, mm	31 (12-58)	30 (13-54)	32 (13-59)	0 (-9-7)	0 (-7-12)	0.2
SpA, n=322						
BASDAI, mm	33 (15-51)	27 (12-48)	29 (16-47)	-1 (-7-5)	1 (-5-8)	0.03
CRP, mg/l	3 (1-6)	3 (1-5)	3 (1-5)	0 (-2-1)	0 (-1-1)	0.4
VAS global, mm	34 (16-59)	30 (12-53)	31 (15-53)	-1 (-12-6)	2 (-6-14)	0.04
ASDAS	2.0 (1.3-2.8)	1.9 (1.2-2.7)	1.9 (1.3-2.7)	-0.1 (-0.4-0.2)	0.1 (-0.4-0.5)	0.1
Reasons for withdrawal during $\geq$ 5 months follow-up (n=129)						
Lack of effect 59, Adverse event 42 (rash 5, diarrhea 3, unspecified/other 34), remission 2, cancer 4, death 1, other/unknown 21						
*Delta values for disease activity pre-switch vs. post-switch, Wilcoxon matched-pair signed rank test						

Conclusions: In 1548 patients with inflammatory rheumatic diseases treated with ETA for >5 years, disease activity was largely unaffected in the majority of patients 3 months after non-medical switch to SB4 and comparable to the fluctuations observed in the 3 months prior to the switch. Several patients (~9%)