Results: Overall, 740 and 539 pts were randomised to IV GLM and PBO groups, respectively. The % of IV GLM vs PBO pts reported the following across studies: infusion reactions (2.8 vs 0.2); SAEs (3.8 vs 2.4); infections (23.8 vs 17.3); serious infections (0.8 vs 0.4) and malignancies (0.1 vs 0.4). No deaths occurred in IV GLM group through wk24. Pts on IV GLM (n=574) vs PBO (n=391) w/concomitant MTX had similar proportions of serious infections (0.9 vs. 0.6). In IV GLM (n=349) vs PBO (n=224) pts who received CS, serious infections were 1.1% vs 0.9%; in pts who did not receive CS, serious infections were 0.5% vs 0%. In IV GLM pts w/ normal ALT at baseline, 30% had postbaseline ALT elevation w/concomitant MTX vs 28% w/o. CS use had inconsistent effect on ALT elevations. Overall incidence of ADAs via drug tolerant assay was 20% (19% w/ MTX and 25% w/o MTX) through wk20 across RA, PsA and AS studies.

	RA		PsA		AS		ALL	
	IV GLM	PBO	IV GLM	PBO	IV GLM	PBO	IV GLM	PBO
Treated Pts	395	197	240	239	105	103	740	539
Age in years, Mean (Range)	51.9 (18-83)	51.4 (19-78)	45.7 (19-69)	46.7 (18-79)	38.4 (19-64)	39.2 (20-67)		
Disease Duration in Years, Mean (SD)	6.9 (7.00)	7.0 (7.24)	6.2 (6.03)	5.3 (5.92)	5.6 (6.57)	5.5 (5.93)		
Avg duration of follow-up (wks)	23.6	20.9	23.9	23.2	16.1	16.0	22.6	21.0
Pts w/≥1 infusion reaction, n (%)	14 (3.5)	1 (0.5)	4 (1.7)	0	3 (2.9)	0	21 (2.8)	1 (0.2)
Pts w/≥1 SAE, n (%)	19 (4.8)	5 (2.5)	7 (2.9)	8 (3.3)	2 (1.9)	0	28 (3.8)	13 (2.4)
Pts w/≥1 infection, n (%)	119 (30.1)	48 (24.4)	45 (18.8)	37 (15.5)	12 (11.4)	8 (7.8)	176 (23.8)	93 (17.3)
Pts w/≥1 serious infection, n (%)	4 (1.0)	0	1 (0.4)	2 (0.8)	1 (1.0)	0	6 (0.8)	2 (0.4)
Pts w/≥1 malignancy, n (%)	1 (0.3)	0	0	2 (0.8)	0	0	1 (0.1)	2 (0.4)
Deaths, n (%)	0	1 (0.5)	0	2 (0.8)	0	0	0	3 (0.6)
% ADA positive*	21		20		19		20	

*w/drug tolerant assay

Conclusions: IV GLM demonstrates the expected safety profile across RA, PSA and AS clinical trials in the PBO-controlled period. Differences between studies may be related to age, use of concomitant medications and disease indication.

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FRI0129

SWITCH BETWEEN REFERENCE ETANERCEPT (ETN) AND GP2015, AN ETANERCEPT BIOSIMILAR, DID NOT IMPACT EFFICACY AND SAFETY IN PATIENTS WITH MODERATE-TO-SEVERE RHEUMATOID ARTHRITIS: 48-WEEK RESULTS FROM THE PHASE 3 EQUIRA STUDY

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Background: GP2015 is an etanercept biosimilar. It has shown an equivalent efficacy, and comparable safety and immunogenicity to ETN in patients with chronic plaque-type psoriasis.¹

Objectives: To compare the efficacy and safety of GP2015 versus ETN in patients with moderate-to-severe rheumatoid arthritis (RA) and evaluate the effects of switching from ETN to GP2015.

Methods: EQUIRA was a 48 week, randomised, double-blind, Phase 3 study. The primary endpoint was equivalent change from baseline (BL) in DAS28-CRP at Week 24. Patients ≥18 years with active RA ACR 1987 or ACR^{EULAR} 2010 criteria for ≥6 months before BL and active disease defined as DAS28-CRP ≥3.2 and CRP >5 mg/L or ESR ≥28 mm/h and inadequate response to methotrexate (MTX) were randomised 1:1 to 50 mg GP2015 or ETN subcutaneously once weekly for 24 weeks (Treatment period 1). Patients with at least moderate EULAR response at Week 24 either continued GP2015 treatment or, in the ETN group, were switched to receive 50 mg GP2015 up to 48 weeks (Treatment period 2 [TP2]). All patients continued to receive concomitant MTX (10–25 mg/week) at a stable dose and folic acid. Efficacy outcome measures included change in DAS28-CRP, EULAR and ACR20/50/70 responses.

Results: Baseline characteristics were comparable between the GP2015 (n=186) and ETN (n=190) groups. The primary endpoint for equivalence was met.² The mean change in DAS28-CRP from BL to Week 48 was comparable between the continued and switched to GP2015 groups (TP2 per-protocol set; figure 1). At Week 48, the EULAR and ACR 20/50/70 response rates were comparable between the two groups (table 1). In TP2, treatment-emergent adverse events (AEs) occurred in 42.9% vs 38.0% patients in the continued GP2015 (n=175) vs the switched (n=166) groups; serious AEs occurred in 2.3% vs 2.4% patients (TP2 safety set). Injection site reactions occurred in 6 (3.6%) patients in the switched group but none in the continued GP2015 group. In TP2, 4 (2.4%) patients in the continued GP2015 group had single-event, very low titer, non-neutralising antidrug antibodies detected.

Abstract FRI0129 – Table 1. Efficacy response over 48 weeks, TP2 per-protocol set (W=week)

Variables	Time	Continued GP2015 n=148	Switched to GP2015 n=131
EULAR good response, n (%)	W48	80 (54.4)	67 (51.9)
EULAR moderate response, n (%)	W48	61 (41.5)	57 (44.2)
ACR20 response, n (%)	W4	70 (47.9)	70 (53.8)
	W12	114 (78.1)	100 (76.9)
	W24	132 (89.8)	122 (93.1)
	W36	128 (87.7)	114 (87.0)
	W48	131 (89.1)	108 (82.4)
ACR50 response, n (%)	W4	19 (13.0)	26 (20.0)
	W12	48 (32.9)	61 (46.9)
	W24	93 (63.3)	96 (73.3)
	W36	90 (61.6)	83 (63.4)
	W48	93 (63.3)	86 (65.6)
ACR70 response, n (%)	W4	6 (4.1)	6 (4.6)
	W12	18 (12.3)	24 (18.5)
	W24	50 (34.0)	60 (45.8)
	W36	47 (32.2)	50 (38.2)
	W48	54 (36.7)	55 (42.0)

Abstract FRI0129 – Figure 1. Change from Baseline in DAS28-CRP up to Week 48 (TP2 per-protocol set)

Conclusions: The efficacy of GP2015 was comparable to that of ETN. Moreover, the switch from ETN to GP2015 did not impact on efficacy and safety of etanercept in patients with moderate-to-severe RA.

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