vs <65 yrs. Through W52, 66% of IV GLM pts and 62% of IFX pts discontinued the study. Discontinuation due to lack of efficacy was generally similar across age groups within treatment groups, although somewhat higher for IV GLM (29%) vs IFX (19%). For both treatments, AEs and discontinuations due to AE through W52 were more common in pts ≥65 vs <65 yrs (Table 1). Consistent with general trends observed in elderly individuals,¹ rates of serious AEs (SAEs) and serious infections increased with age for both IV GLM and IFX; however, increases were more notable in IFX- than IV GLM-treated pts ≥65 yrs. The incidence of serious infections was highest in pts ≥75 yrs for both treatments, although small sample size may limit data interpretation. No increase in opportunistic infections, including Varicella, was observed in pts ≥65 vs <65 yrs. Infusion reactions were more common in pts <65 yrs in both treatment groups, and more prevalent in IFX- than IV GLM-treated pts within each age group through W52. Generally similar safety results were seen between W52 and W104 for each treatment group (data not shown). Both IV GLM and IFX in bionative pts showed improvement in CDAI scores across age groups, which was maintained over time (Figure 1).

Table 1. % of pts with ≥1 AE through W52 DBL

	IV GLM			IFX		
	<65 yrs	≥65 yrs	≥75 yrs	<65 yrs	≥65 yrs	≥75 yrs
Patients, n	351	334	91	370	215	46
Discontinued due to AE	8.5%	12.6%	16.5%	15.1%	17.7%	21.7%
AE	52.4%	58.4%	57.1%	63.5%	66.5%	71.7%
Most common AEs (≥5% of pts in either treatment group)						
Nausea	3.7%	3.3%	3.3%	8.4%	6.0%	2.2%
Worsening of RA	5.4%	4.5%	3.3%	7.3%	7.0%	4.3%
Upper respiratory tract infection	5.7%	5.1%	4.4%	6.2%	5.6%	2.2%
Pruritis	1.4%	2.4%	3.3%	6.8%	2.8%	2.2%
Sinusitis	7.1%	3.3%	0%	3.8%	3.7%	2.2%
Urinary tract infection	4.8%	5.1%	5.5%	4.3%	5.1%	6.5%
SAE	7.7%	16.8%	20.9%	9.7%	18.6%	26.1%
Infection	30.5%	27.2%	27.5%	32.2%	28.8%	32.6%
Serious infection	3.7%	6.3%	7.7%	3.5%	7.9%	15.2%
Neoplasms benign, malignant and unspecified	0.6%	2.7%	1.1%	0.8%	2.3%	6.5%
Latent tuberculosis	0.3%	0%	0%	0.3%	0%	0%
Opportunistic infection	1.4%	1.8%	4.4%	1.9%	1.4%	4.3%
Infusion reaction	5.1%	2.7%	1.1%	17.3%	8.8%	8.7%
Death	0.3%	2.4%	2.2%	0%	2.3%	6.5%

Figure. Mean (SD) change from baseline CDAI score at 6 months and 12 months (observed data) for bionative population^a

^a Efficacy conducted for bionative population including pts who had IFX dose escalation

Conclusion: Elderly RA pts receiving IV GLM or IFX in this RWE study demonstrated similar safety and efficacy as reported in Phase 3 trials.^{2,3} The higher rates of AEs, discontinuations due to AE, and SAEs (mainly serious infections) observed in pts ≥65 yrs are in line with increased safety events seen in elderly vs younger individuals in the general population. Rates of AEs, SAEs, and infusion reactions were higher for IFX vs IV GLM. Infusion reactions were more common in pts <65 vs ≥65 yrs for both GLM and IFX, but more prevalent with IFX.

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POS0591

SARILUMAB ATTENUATES DISEASE ACTIVITY IN SERONEGATIVE RA PATIENTS – PRELIMINARY DATA FROM A NON-INTERVENTIONAL STUDY IN REGULAR CARE IN GERMANY

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Background: Although seronegative RA patients often present with substantial disease burden [1], patients are underrepresented in research cohorts or clinical trials. Consequently, less knowledge about this subgroup has been accumulated.

Objectives: To describe outcome of seronegative vs. seropositive RA patients treated with sarilumab in regular care in Germany.

Methods: The prospective, observational, 24-month single-arm PROSARA study (SARIL08661) is currently running in Germany at 96 sites, aiming to enroll up to 750 RA patients treated with sarilumab. RA patients are prospectively selected at physician's discretion according to label, and medical history is documented before treatment. This interim analysis included patients with data available up to 24 months. Here we focus on sustained treatment response after 6 and 12 months, respectively. Patients were stratified according to serostatus (RF- AND ACPA- as seronegative or RF+ AND/OR ACPA+ as seropositive). All analyses are descriptive only.

Results: To date 473 patients were included in the study, of which 22.2% (n=105) were seronegative and 59.0% (n=279) were seropositive (Table 1). For 89 patients (18.8%) serostatus was not specified.

The mean time since diagnosis of RA was shorter in seronegative than in seropositive patients (7.9±7.6 years vs. 11.5±9.9 years) (Table 1).

At baseline, CDAI score was 27.7±14.7 (n=104) and 23.0±12.9 (n=272) in seronegative and seropositive patients, respectively. After 12 months of sarilumab treatment, CDAI improved to 15.6±12.3 (n=38) and 9.1±8.7 (n=101) in seronegative and seropositive, respectively, for patients with post-baseline data available. At that time, remission/low disease activity according to CDAI was reached by 5.3% (n=2/38) / 39.5% (n=15/38) of seronegative patients, respectively and by 26.7% (n=27/101) / 68.3% (n=69/101) of seropositive patients, respectively (Fig. 1A, B).

Physical function, assessed by HAQ-DI, was slightly more impaired in seronegative patients (1.4±0.7) than in seropositive patients (1.2±0.7) at baseline. HAQ-DI improved over 12 months to 0.9±0.7 in seropositive patients (n=90) but showed no change in seronegative patients (1.4±0.7; n=37) (Fig. 1C).

Safety was consistent with the anticipated profile of IL-6-R-inhibition and no new safety signals occurred. Adverse events and serious adverse events were described in 61.7% and 12.8% of seronegative patients, respectively and in 55.2% and 13.7% of seropositive patients, respectively.

Table 1. Baseline data regarding patient characteristics, prior treatment and disease activity

patient characteristics		seronegative		seropositive	
		patients [n] (%)		patients [n] (%)	
prior RA treatment	patients [n] (%)	105 (22.2)		279 (59.0)	
	Sex female [n] (%)	81 (77.1)		207 (74.2)	
	Age mean [years] (SD)	56.6 (12.5)		59.6 (10.9)	
	BMI mean (SD) [kg/m ²]	29.2 (6.7)		28 (6.0)	
	Smoking history current/former [%]	22.1/11.5		25.5/20.4	
disease activity	Time since diagnosis of RA mean [years] (SD)	7.9 (7.6)		11.5 (9.9)	
	csDMARD [n] (%)	102 (97.1)		273 (97.8)	
	bDMARD (TNFi) [n] (%)	54 (51.4)		167 (59.9)	
	bDMARD (non-TNFi) [n] (%)	32 (30.5)		83 (29.7)	
	tsDMARD (JAKi) [n] (%)	25 (23.8)		57 (20.4)	
disease activity	CRP [mg/l] (SD)	12.9 (20.9)		14.2 (31.0)	
	ESR [mm/h] (SD)	23.7 (20.5)		25.3 (22.4)	
	SJC mean (SD)	5.3 (5.5)		4.6 (4.8)	
	TJC mean (SD)	10.2 (8.2)		7.2 (6.6)	
	HAQ-DI mean (SD)	1.4 (0.7)		1.2 (0.7)	
	DAS28-ESR mean (SD)	5.0 (1.5)		4.6 (1.5)	
	CDAI mean (SD)	27.7 (14.7)		23.0 (12.9)	
	Fatigue [VAS] (SD)	64.0 (25.5)		51.1 (28.1)	

Fig. 1 only shows patients with post-baseline data available (full analysis set) and therefore differs slightly to baseline data in Tab. 1 (baseline analysis set)
BL=baseline

Figure 1. CDAI (A, B) and HAQ-DI (C) outcomes in seronegative and seropositive patients

Conclusion: Sarilumab treatment ameliorated CDAI in both seronegative (Δ CDAI -17.0 ± 16.5) and seropositive (Δ CDAI -15.4 ± 14.3) patients to the same extent over the course of 12 months, with a higher remission rate in seropositive patients. Functional capacity improved meaningfully in the seropositive cohort but had no significant impact in seronegative patients. The safety profile was consistent with data reported from controlled clinical trials.

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POS0592

BIOSIMILAR INFlixIMAB THERAPY IN RHEUMATOID ARTHRITIS, ANKYLOSING SPONDYLITIS AND PSORIATIC ARTHRITIS: A LONG-TERM FOLLOW-UP STUDY ON INFlixIMAB-NAÏVE PATIENTS AND PATIENTS SWITCHED FROM THE ORIGINATOR TO THE BIOSIMILAR CT-P13

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Objectives: The ReFLECT study was carried out to investigate real life use of CT-P13, the first monoclonal antibody biosimilar to infliximab originator.

Methods: ReFLECT is a multicentre, prospective, observational study conducted in France to determine the characteristics of patients (pts) receiving CT-P13, its effectiveness and safety in a real-life setting. Eligible were both pts who had been switched from infliximab originator (IFX_S) and infliximab-naïve pts started on CT-P13 (IFX_N). Intermediate results in pts with rheumatic diseases using descriptive statistical analyses from inclusion to a 24-month-follow-up period are described here.

Results: Among the 1370 adult pts included between October 2016 and April 2019, data were analysed for 142 pts with rheumatoid arthritis (RA; 23.9% males; mean age: 61.5±10.9 years; 80 IFX_N/61 IFX_S), 411 with ankylosing spondylitis (AS; 58.9% males; 48.1±13.1 years; 228 IFX_N/179 IFX_S), and 96 with psoriatic arthritis (PsA; 41.7% males; 53.4±14.1 years; 55 IFX_N/40 IFX_S) after a median of between 8.7 and 12.9 years since diagnosis. At inclusion, 66.9%, 24.3% and 50% had one concomitant treatment, mainly methotrexate. At the time of the first administration of CT-P13, disease had been active in 94.2%, 76.6% and 83.3% of the IFX_N pts compared with 45.3%, 24.0% and 32.0% of the IFX_S pts. After 24 months of follow-up, both CRP levels and disease activity remained stable compared to baseline in the IFX_S pts: median Δ CRP/RA_S = 1, Δ CRP/AS_S = 0, Δ CRP/PsA_S = 0 and median Δ DAS28/RA_S = 0, Δ BASDAI/AS_S = 0, Δ DAS28/PsA_S = 1. As expected, improvement was observed in the IFX_N pts: median Δ CRP/RA_N = -2, Δ CRP/AS_N = -2, Δ CRP/PsA_N = 0 and median Δ DAS28/RA_N = -1, Δ BASDAI/AS_N = -2, Δ DAS28/PsA_N = -1. In naïve pts, CT-P13 brought both CRP and disease activity down to levels comparable to those seen in patients switched from the IFX originator: median [Q1;Q3] CRP/RA_N = 5 [2;9] vs CRP/RA_S = 5 [2;8]; CRP/AS_N = 3 [2;9] vs CRP/AS_S = 3 [2;5]; CRP/PsA_N = 2 [1;4] vs CRP/PsA_S = 2 [1;3] and median [Q1;Q3] DAS28/RA_N = 3 [3;4] vs DAS28/RA_S = 2 [2;3]; BASDAI/AS_N = 3 [1;4] vs BASDAI/AS_S = 2 [1;3]; DAS28/PsA_N = 3 [2;3] vs DAS28/PsA_S = 3 [2;3], (Figure 1). At 24 months, 62.7%, 74.9% and 75.0% remained on treatment with CT-P13 in RA, AS and PsA pts respectively. The reasons for treatment withdrawing and safety results are reported in Table 1.

Figure 1. Disease activity at the time of first administration of CT-P13 and after 24 months**Table 1. Reasons for treatment withdrawing and safety results**

Reasons for treatment withdrawing						
IFX pts, n (%)	RA _N , 37	RA _S , 15	AS _N , 64	AS _S , 38	PsA _N , 11	PsA _S , 12
Missing	1	0	0	0	0	1
Remission	0	2 (13.3)	2 (3.1)	0	0	0
Therapeutic failure *	25 (69.4)	8 (53.3)	41 (64.1)	23 (60.5)	5 (45.5)	6 (54.5)
Intolerance	5 (13.9)	1 (6.7)	5 (7.8)	2 (5.3)	1 (9.1)	1 (9.1)
Other	6 (16.7)	4 (26.7)	16 (25.0)	13 (34.2)	5 (45.5)	4 (36.4)
Safety data, n (%)						
RA, 142	AS, 411					
Pts with ≥ 1 adverse event (AE)	67 (47.2)	222 (54.0)				
Pts with ≥ 1 AE related to CT-P13	33 (23.2)	84 (20.4)				
Pts with ≥ 1 serious AE	19 (13.4)	42 (10.2)				
Pts with ≥ 1 allergic infusion reaction †	4 (2.8)	11 (2.7)				
Pts with ≥ 1 infection ‡	10 (7.0)	18 (4.4)				
					3 (3.1)	

* Encompassing primary failure in IFX_N pts and loss of efficacy in IFX_N and IFX_S pts† Including acute and delayed hypersensitivity reactions‡ Including severe infections, tuberculosis, opportunistic infections, hepatitis

Conclusion: Year 2 follow-up data indicate that CT-P13 effectively induced improvement in disease activity in pts with RA, AS and PsA receiving infliximab for the first time and maintained stable disease activity in pts switched from