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SAT0194 SIRUKUMAB INTEGRATED SAFETY IN RHEUMATOID ARTHRITIS PATIENTS: ANALYSIS OF THE SIRROUND PHASE 3 DATA

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Background: Sirukumab (SIR), a human monoclonal antibody that selectively binds the IL-6 cytokine, is in development for the treatment of rheumatoid arthritis (RA). Efficacy of SIR was shown in several phase 3 trials in RA patients (pts; SIRROUND program).

Objectives: To analyze safety data from completed/ongoing studies in the SIRROUND program.

Methods: Safety comparisons included SIR 50mg q4w and 100mg q2w doses vs placebo (pbo) in the pbo-controlled period (Wk 0–18) of 2 phase 3 studies. A long-term comparison of the safety of SIR 50mg q4w and 100mg q2w for the entire program was also performed.

Results: In phase 3 studies, 2926 pts received SIR for up to 3.4y (median duration, 1.46y). During Wk 0–18, there were more adverse events (AEs), AEs leading to discontinuation, and serious AEs (SAEs) with SIR vs pbo, with cumulative rates of SAEs remaining constant over time (Table). In general, no dose effect with SIR was observed in the 18-wk or long-term analysis. Mortality rates were similar across treatment groups through 18 wks and remained stable in long-term analysis. Serious infections were more frequent in SIR-treated pts vs pbo during Wk 0–18, with similar rates through long-term analysis. Rates of gastrointestinal (GI) perforations and malignancies were low and similar across groups during the 18-wk and long-term analysis; major adverse cardiovascular event (MACE) rates were similar through 18 wks and numerically higher with SIR 50mg q4w vs 100mg q2w in long-term analysis.

Conclusions: SIR is well tolerated in pts with moderately to severely active RA. Overall, no dose relationship was observed between SIR 50mg q4w and 100mg q2w for types or frequencies of AEs.

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SAT0195 RITUXIMAB SHOWS BETTER SUSTAINABILITY THAN TNF INHIBITORS WHEN USED FOLLOWING INITIAL BIOLOGIC DMARD FAILURE IN THE TREATMENT OF RHEUMATOID ARTHRITIS: 8 YEARS OF REAL-WORLD OBSERVATIONS FROM THE RHUMADATA® CLINICAL DATABASE AND REGISTRY

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Background: In the absence of biomarkers predicting response to a specific therapy, the choice of second biologic is based mostly on habit and availability of an alternative agent. Traditionally, a second anti-TNF was the preferred option,

Abstract SAT0194 – Table 1. Treatment-emergent AEs in Phase 3 Studies

	Wk 0–18			Long-term analysis (Wk 0-safety cutoff)	
Ine	Pbo (N=850)	SIR 50mg q4w (N=848)	SIR 100mg q2w (N=850)	SIR 50mg q4w (N=1461)	SIR 100mg q2w (N=1465)
AEs, n (%)	444 (52.2)	515 (60.7)	548 (64.5)	1207 (82.6)	1237 (84.4)
AEs leading to discontinuation, n (%)	22 (2.6)	34 (4.0)	45 (5.3)	174 (11.9)	196 (13.4)
SAEs, n (%)	27 (3.2)	41 (4.8)	46 (5.4)	265 (18.1)	268 (18.3)
Incidence*	9.36 (6.17–13.61)	14.36 (10.30–19.48)	16.14 (11.82–21.53)	13.12 (11.58–14.79)	13.12 (11.60–14.79)
Serious infection, n (%)	7 (0.8)	16 (1.9)	14 (1.6)	102 (7.0)	101 (6.9)
Incidence*	2.40 (0.97–4.95)	5.52 (3.15–8.96)	4.81 (2.63–8.07)	4.76 (3.88–5.77)	4.67 (3.81–5.68)
GI perforation, n (%)	0	1 (0.1)	3 (0.4)	5 (0.3)	9 (0.6)
Incidence*	0 (0–1.02)	0.34 (0.01–1.91)	1.02 (0.21–2.99)	0.23 (0.07–0.53)	0.41 (0.19–0.77)
MACE, n (%)	2 (0.2)	3 (0.4)	2 (0.2)	20 (1.4)	9 (0.6)
Incidence*	0.68 (0.08–2.47)	1.03 (0.21–3.00)	0.68 (0.08–2.46)	0.92 (0.56–1.42)	0.41 (0.19–0.77)
Malignancy, n (%)	2 (0.2)	1 (0.1)	1 (0.1)	23 (1.6)	19 (1.3)
Incidence*	0.68 (0.08–2.47)	0.34 (0.01–1.91)	0.34 (0.01–1.91)	1.05 (0.67–1.58)	0.86 (0.52–1.35)
Death, n (%)	1 (0.1)	1 (0.1)	1 (0.1)	15 (1.0)	14 (1.0)
Incidence*	0.34 (0.01–1.91)	0.34 (0.01–1.91)	0.34 (0.01–1.90)	0.68 (0.38–1.13)	r 0.63 (0.35–1.06)

*Incidence per 100 pt-years (95% CI).

Abstract SAT0195 – Table 1. First bDMARD history and Retention Characteristics of Second bDMARD used

	Second bDMARD					
	TNFi			Rituximab		
First bDMARD Failed	Failure type		All	Failure type		All
	Primary	Secondary		Primary	Secondary	
TNF inhibitor	41 (25.5%)	120 (74.5%)	161 (100.0%)	17 (28.8%)	42 (71.2%)	59 (100.0%)
Other mode of action	6 (18.2%)	27 (81.8%)	33 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Total	47 (24.2%)	147 (75.8%)	194 (100.0%)	17 (28.8%)	42 (71.2%)	59 (100.0%)
Second bDMARD Retention Probability at:						
6 Months		64.68% (3.45%)			96.15% (2.67%)	
12 Months		50.54% (3.61%)			88.05% (4.59%)	
24 Months		39.77% (3.59%)			85.84% (4.97%)	
60 Months		22.26% (3.53%)			72.44% (6.95%)	
96 Months		13.22% (3.62%)			72.44% (6.95%)	
Biologic Retention Time (years)						
Mean, mean (SE)		2.71 (0.25)			6.73 (0.46)	
Lower Quartile, (95% CI)		0.36 (0.28–0.44)			4.18 (1.51–8.48)	
Median, (95% CI)		1.08 (0.71–1.60)			– (8.42 –)	
Upper Quartile, (95% CI)		4.26 (3.25–6.64)			– (–)	