REFERENCES:

Table 1.

	MI-2 (n=5)	PL-7 (n=6)	PL-12 (n=4)	Jo-1 (n=6)	MDA5 (n=1)	antiRo52 (n=57)	SRP (n=3)	Scl-70 (n=12)	CENP (n=14)	Th(n=2)	Ku (n=14)	Fibrilarina (n=2)	PM-Scl75/100 (n=23)	NOR90 (n=8)	RNA pol (n=2)
ILD	0	4 (66.7)	4 (100)	3 (50)	1 (100)	19 (33.3)	0	7 (58.3)	1 (7.1)	0	7 (50)	1 (50)	9 (39.1)	5 (62.5)	0
Cancer	1 (20)	0	0	0	0	6 (10.5)	1 (33.3)	0	0	0	1 (7.1)	0	0	0	0

FIGURE 1

Disclosure of Interests: None declared

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EXPLORING THE UTILITY OF THE AMERICAN COLLEGE OF RHEUMATOLOGY (ACR) CRIS IN PATIENTS WITH DIFFUSE CUTANEOUS SYSTEMIC SCLEROSIS

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Background: The ACR Composite Response Index in diffuse cutaneous Systemic Sclerosis (CRISS) was developed to measure the probability of improvement in response to treatment in patients with early diffuse cutaneous SSc (dcSSc), accounting for new/worsening cardiopulmonary involvement and/or renal crisis, and changes in modified Rodnan skin score, forced vital capacity, health assessment questionnaire disability index, and patient's and physician's global impressions. In patients with SSc-ILD, treatment response may be reflected as slower progression, stabilisation or improvement.

Objectives: Using data from patients with dcSSc and ILD in the placebo group of the SENSICIS trial, we analysed the probability of improvement using the ACR CRISS score at week 52. We also evaluated whether the CRISS numerator could provide information on the spectrum of responses in this patient population.

Methods: The SENSICIS trial enrolled subjects with SSc-ILD with onset of first non-Raynaud symptom ≤7 years before screening, FVC ≥40% predicted, and fibrotic ILD ≥10% extent on an HRCT scan. Subjects on prednisone ≤10 mg/day (or equivalent) and/or stable therapy with mycophenolate or methotrexate were allowed to participate. Subjects were randomised to receive nintedanib or placebo. Subjects were not randomised by use of mycophenolate. In patients randomised to receive placebo who had dcSSc and/or mRSS >15 at baseline, we analysed the ACR CRISS and its numerator at week 52 in subgroups by use of mycophenolate at baseline. Analyses were exploratory and descriptive.

Results: Of 117 analysed subjects in the placebo group who had dcSSc and/or mRSS >15 at baseline, 60 (51.3%) were taking mycophenolate at baseline. Compared with patients not taking mycophenolate at baseline, those taking mycophenolate had a lower mean age (48.4 [SD 11.8] vs 53.1 [13.4] years), lower mean FVC % predicted (68.8 [17.0] vs 73.0 [14.6]), and a greater proportion were

female (76.7% vs 71.9%); median time since first onset of non-Raynaud symptom was similar (3.9 vs 4.5 years, respectively) as was mean (SD) mRSS (16.5 [7.7] vs 15.9 [8.0], respectively). One patient (taking mycophenolate at baseline) had limited cutaneous SSc. At week 52, median (Q1, Q3) ACR CRISS score was 0.036 (0.001, 0.601) in subjects taking mycophenolate and 0.002 (0.000, 0.112) in subjects not taking mycophenolate at baseline, and mean (SD) ACR CRISS score was 0.28 (0.37) in subjects taking mycophenolate and 0.16 (0.31) in subjects not taking mycophenolate at baseline (Figure 1). In these groups, respectively, 25.0% and 14.0% of subjects had CRISS score >0.6 (considered improved) at week 52. The CRISS numerator provided a broader distribution of response values, but was not informative in this patient population.

Conclusion: In exploratory analyses, among subjects with dcSSc and ILD who received placebo in the SENSICIS trial, the proportion considered improved at week 52 based on ACR CRISS score was numerically greater in patients taking than not taking mycophenolate at baseline. There remains a need for composite scores that provide better interpretation of the magnitude of response in patients with SSc.

Figure. Box-and-whisker plot of CRISS score at week 52 in subjects with SSc-ILD with dcSSc and/or mRSS >15 at baseline in the placebo group of the SENSICIS trial by use of mycophenolate at baseline

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