was analyzed by using an analysis of covariance (ANCOVA). Non-inferiority is to be concluded if the lower bound of the 95% CI for the treatment difference in the change of DAS28 (CRP) from baseline to Week 22 is greater than the pre-specified NI margin of -0.6.

Results: A total of 362 patients were enrolled, of whom 348 were randomly assigned at Week 6 into 2 treatment arms in a 1:1 ratio (169 and 179 patients in SC 120 mg and IV 3 mg/kg arms, respectively). The mean change of DAS28 (CRP) from baseline to Week 22 was similar between the arms. The lower limit of two-sided 95% CI (0.03) was greater than the pre-specified NI margin (-0.6) which indicated NI of SC 120 mg compared to IV 3 mg/kg (Table 1). Additional efficacy including ACR responses were similar between two treatment arms up to Week 22 with slightly higher response rate trend observed in SC 120 mg arm at Week 30 (Figure 1). The safety profiles which occurred after study drug administration at Week 6 in SC 120 mg arm were generally comparable to IV 3 mg/kg arm. All of injection site reactions were grade 1 or 2 in intensity. Majority of administration-related reactions (ARRs) were grade 1 or 2 in intensity except 1 patient in IV 3 mg/kg arm who experienced grade 3 ARR and was withdrawn from the study due to this event (Table 2).

Table 1. Analysis of Change (decrease) from Baseline of DAS28 (CRP) at Week 22 (ANCOVA)

Treatment	n	DAS28 (CRP) decrease Least Square Mean (Standard Error)	Estimate of Treatment Difference	95% CI of Treatment Difference
SC 120 mg	164	2.22 (0.221)	0.28	(0.03, 0.53)
IV 3 mg/kg	171	1.95 (0.209)		

Note. Country, Week 2 serum CRP concentration (≤ 0.6 mg/dL vs >0.6 mg/dL), and Week 6 body weight (≤ 100 kg vs >100 kg) were considered as covariates.

Table 2. Summary of Safety Results up to from Weeks 6 to 30

Safety, n (%)		SC 120 mg (N=170)	IV 3 mg/kg (N=178)
	Treatment-emergent AEs	62 (36.5)	76 (42.7)
	Administration-related reactions	1 (0.6)	8 (4.5)
	Injection site reactions	11 (6.5)	4 (2.2)
	Infections	34 (20.0)	32 (18.0)

Note. One patient in IV 3 mg/kg arm was analyzed as SC 120 mg arm in Safety Population as receiving CT-P13 SC at Week 14.

Figure 1. The proportion of patients Achieving Clinical Response according to the ACR Criteria up to Week 30

Note. Results at Week 2 and Week 6 were obtained following IV infusion in the Dose-Loading Phase.

Conclusion: The study demonstrated NI of efficacy for CT-P13 SC to the CT-P13 IV. Also, CT-P13 SC showed similar efficacy and safety profiles to CT-P13 IV up to Week 30. CT-P13 SC could provide a favorable benefit to patients with an alternative convenient way of administration.

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SAT0171 A RETROSPECTIVE ANALYSIS OF LONG TERM SAFETY UP TO FIVE YEARS OF INFLIXIMAB BIOSIMILAR CT-P13 IN PATIENTS WITH RHEUMATOID ARTHRITIS AND ANKYLOSING SPONDYLITIS

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Background: Long term safety and efficacy of anti-TNF inhibitors in rheumatic diseases is an important aspect of patient treatment. CT-P13 is the first infliximab biosimilar approved by EMA and FDA and has demonstrated comparable efficacy and safety with reference infliximab in rheumatoid arthritis (RA)^{1,2} and ankylosing spondylitis (AS)^{3,4}. However, long term data of infliximab biosimilar to date has been limited to two years^{5,6}.

Objectives: To demonstrate drug survival and long term safety and efficacy of CT-P13 up to 5 years in patients with RA or AS, including patients who switched from reference infliximab to CT-P13.

Methods: Long term data was retrospectively collected from medical records of patients with RA and AS treated with CT-P13 at least once between September 2012 and December 2017 in five referral hospitals in Korea. Patients included both those who were infliximab-treatment naïve at the start of CT-P13 treatment (naïve patient) and those who switched from reference infliximab to CT-P13 (switched patient). Primary endpoints were safety and drug survival up to 5 years analyzed by Kaplan-Meier curve.

Results: Data from 491 patients (154 RA and 337 AS) were collected and analyzed, including 19 and 118 switched patients with RA and AS, respectively. Median disease duration was 64.7 months (range: 4.7 to 265.9 months) for patients with RA and 56.3 months (range: 3.0 to 216.7 months) for patients with AS. The median duration of CT-P13 treatment was 46.8 weeks (range: 0 to 250.6 weeks) and 94.1 weeks (range: 0 to 246.0 weeks) for patients with RA and AS, respectively. The probability of survival at year 5 for patients with RA was 0.42 and 0.53 respectively for naïve and switched patients. The probability of survival at year 5 for patients with AS was 0.64 and 0.72 respectively for naïve and switched patients. Median DAS28-ESR score decreased from 5.80 at baseline to 2.73 at year 5 and median DAS28-CRP score decreased from 5.14 at baseline to 1.29 at year 4 for patients with RA. Median BASDAI score decreased from 6.60 at baseline to 3.00 at year 5 for patients with AS. The most common reason for discontinuation for both patients with RA and AS was lack of efficacy. 31.8% of patients with RA and 29.4% of patients with AS experienced at least one adverse event and the most frequently observed type of adverse event was upper respiratory tract infection for 3.90% in patients with RA and 4.15% in patients with AS.

Conclusion: This is the longest evidence to date of safety and efficacy of infliximab biosimilar CT-P13 treatment in patients with RA or AS. Five year analysis of medical records showed that long term treatment with CT-P13 was safe and efficacious based on drug survival, disease activity measurements, and adverse events. Drug survival was similar between patients who were naïve at the start of CT-P13 treatment and switched from reference to CT-P13.

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Figure 1. Drug survival probability of patients with RA treated with CT-P13

Figure 2. Drug survival probability of patients with AS treated with CT-P13

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SLE, Sjögren's and APS – clinical aspects (other than treatment)

SAT0172 ANTIBODIES TO BOTH RO52 AND RO60 DEFINE A SUBSET OF SJÖGREN'S MOST SUITABLE FOR CLINICAL TRIALS OF AGENTS TARGETING LYMPHOPROLIFERATIONS

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Background: Anti-SSA antibodies comprise reactivity to two distinct proteins, Ro52 and Ro60, encoded by separate genes and found on separate ribonucleoprotein particles. Specific testing for Ro52 and Ro60 antibodies is now clinically available, yet the phenotypic correlates of Ro52 and Ro60 reactivity profiles have not been well defined.

Objectives: To determine the phenotypic correlates of antibody reactivity to Ro52 alone, Ro52 + Ro60, and Ro60 alone in patients being evaluated for Sjögren's syndrome (SS).

Methods: We initially studied 840 patients seen at the Hopkins Sjögren's Syndrome Center with suspected or established SS. Each had serum tested for antibodies to recombinant Ro52 (Inova Quanta Lite ELISA) and Ro60 (IVTT immunoprecipitation). We then validated our findings in a

second cohort consisting of 194 patients, each with testing for antibodies to recombinant anti-Ro52 and anti-Ro60 by a chemiluminescent assay (Inova Bioflash). Statistical analyses were performed using JMP pro 13. The Chi-square or Fisher exact test was used to compare the groups.

Results: The discovery cohort of 840 patients included 751 (89%) women, with a mean age of 58.5±13.5 years. 371 (44%) patients met the ACR/EULAR classification criteria. There were 311 with anti-Ro52 +Ro60, 108 with anti-Ro60 alone, 95 with anti-Ro52 alone, and 326 with neither antibody. The 311 patients with anti-Ro52+Ro60 reactivity had a distinctive phenotype, with a markedly increased prevalence of ANA ≥ 1:320, RF, IgG ≥ 1560 mg/dL, and SS-B positivity (p<0.008 for all inter-group comparisons) and an increased prevalence of focus score ≥ 1 and hypochoic lesions on parotid gland ultrasonography which trended toward statistical significance. These differences were also validated in the second cohort, with the exception of focus score and parotid gland hypochoic lesions, possibly as a result of smaller group numbers. The Ro52 and Ro60 alone groups were equivalent to each other in their phenotypic associations, except for RF, which was higher in the Ro52 alone group. Measures of lacrimal and salivary gland function and the prevalences of extraglandular manifestations did not show consistent differences between the groups or the two cohorts.

Conclusion: Testing anti-Ro52 and anti-Ro60 in patients with suspected or established SS identifies a unique subset, namely those with both Ro52 and Ro60 antibodies, distinguished by a much higher prevalence of B-cell activation markers and glandular inflammation as measured by focus score and hypochoic lesions. This subset may be most suitable for inclusion in clinical trials where the therapeutic agent targets glandular lymphoproliferation.

Table: The comparison of the differences according to anti-Ro subtypes in 2 different cohorts									
	Discovery cohort (n=840)				All group comparison		Two group comparison		Validation cohort ¹ (n=194)
	Group A: anti-Ro52 alone n=108 (%)	Group B: anti-Ro60 with anti-Ro52 n=311 (%)	Group C: anti-Ro52 alone n=95 (%)	Group D: All negative n=326 (%)	p value ²	p value ³	Two group comparison	p value ⁴	Two group comparison
ANA ≥ 1:320	25/106 (25.4)	228/297 (76.7)	36/91 (39.5)	41/318 (12.9)	<0.0001		B vs A, <0.0001 B vs C, <0.0001 B vs D, <0.0001 A vs C, 0.0156	B vs A, 0.0004 B vs C, <0.0001 B vs D, <0.0001 A vs C, 0.0366	
Positive RF	11/104 (10.6)	178/306 (58.2)	27/88 (30.7)	20/321 (6.2)	<0.0001		B vs A, <0.0001 B vs C, <0.0001 B vs D, <0.0001 A vs C, 0.0005	B vs A, 0.0003 B vs C, <0.0001 B vs D, <0.0001 A vs C, 0.0009	
IgG ≥ 1560 mg/dL	14/100 (14.0)	135/298 (45.3)	12/87 (13.8)	16/306 (5.2)	<0.0001		B vs A, <0.0001 B vs C, <0.0001 B vs D, <0.0001 A vs C, 0.0675	B vs A, 0.0005 B vs C, 0.0019 B vs D, <0.0001 A vs C, 0.0841	
SSB antibody positivity	16/106 (14.8)	166/311 (53.4)	17/95 (17.8)	23/326 (7.1)	<0.0001		B vs A, <0.0001 B vs C, <0.0001 B vs D, <0.0001 A vs C, 0.0329	B vs A, 0.0031 B vs C, <0.0001 B vs D, <0.0001 A vs C, 0.0265	
FLS with FS ≥ 1	5/78 (6.4)	50/150 (33.3)	17/63 (26.9)	38/288 (13.2)	<0.0001		B vs A, <0.0001 B vs C, 0.0024 B vs D, <0.0006 A vs C, 0.0008	B vs A, 0.1328 B vs C, 0.0027 B vs D, 0.0006 A vs C, 0.0771	
Parotid hypochoic lesions	4/14 (28.6)	43/88 (60.3)	3/14 (21.4)	3/38 (7.9)	<0.0001		B vs A, <0.0001 B vs C, 0.0098 B vs D, <0.0079 A vs C, 0.0625	B vs A, 0.0051 B vs C, 0.1146 B vs D, <0.0001 A vs C, 0.0356	
Extraglandular manifestations	38/108 (35.2)	156/311 (50.1)	41/95 (43.2)	100/326 (30.7)	<0.0001		B vs A, 0.0042 B vs C, 0.1740 B vs D, <0.0001 A vs C, 0.2450	NS in all groups	

RF, rheumatoid factor; FS, focus score; FLS, focal lymphocytic salivary glanditis; SSB, Sjögren's syndrome B antibody; ANA, antinuclear antibody; IgG, immunoglobulin G; A, anti-Ro52 alone; B, anti-Ro52 + Ro60; C, anti-Ro52 alone; D, all negative.

¹ A p-value of 0.05 was considered significant.

² A p-value of 0.05 was considered significant.

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SAT0173 RENAL GALLIUM SCAN CORRELATED WITH INFLAMMATION IN RENAL HISTOLOGY OF PATIENTS WITH LUPUS NEPHRITIS

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Background: Lupus nephritis (LN) is the leading cause of mortality in lupus patients. But there is only one image assessment method, the histopathology through invasive renal biopsy.

Objectives: This study aimed to investigate the clinical value of the non-invasive image assessment method: renal gallium scan, in renal histological parameters of LN in a cohort of one single tertiary referral center.

Methods: Between 2006 and 2018, a hospital-based observational study was conducted to enroll 266 biopsy-proven and 40 repeated-biopsied LN patients who underwent renal gallium scan before biopsy. The classification and scoring of LN were assessed according to the International