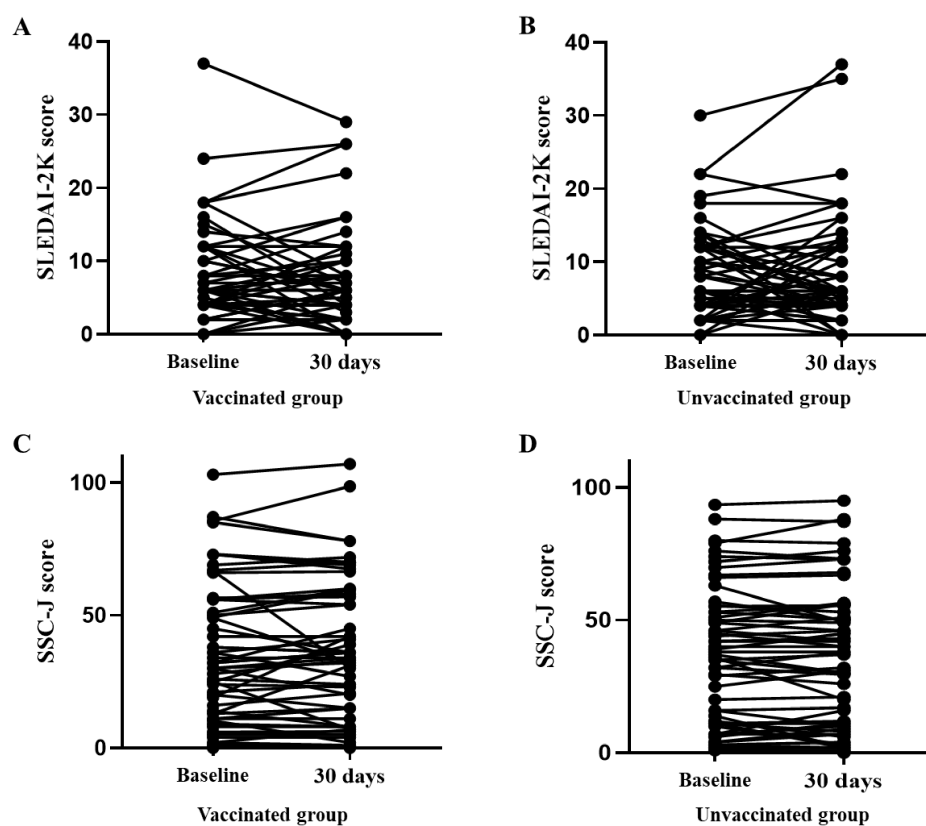


1

SUPPLEMENTAL FIGURE

2 Supplemental Figure 1: Slope graph of changes in SLEDAI-2K and SSC-J scores

3 from baseline to 30 days after the second vaccination



4

5

6 [A-B] SLEDAI-2K score and [C-D] SSC-J score. Disease activities before the first

7 vaccination were set as the baseline. SLEDAI-2K, Systemic Lupus Erythematosus

8 Disease Activity Index-2000; SSC-J, Japanese version of the Systemic Lupus

9 Erythematosus Symptom Checklist Questionnaire

10

SUPPLEMENTAL TABLES11 **Supplemental Table 1: Flare rates at 30, 60, and 90 days after the second vaccination**

12

	Vaccinated	Unvaccinated
	n = 74	n = 74
30 days after the second vaccination		
Major flare, <i>n</i> (%)	0 (0.0)	3 (4.1)
Minor flare, <i>n</i> (%)	15 (20.3)	15 (20.3)
60 days after the second vaccination		
Major flare, <i>n</i> (%)	1 (1.4)	3 (4.1)
Minor flare, <i>n</i> (%)	18 (24.3)	14 (18.9)
90 days after the second vaccination		
Major flare, <i>n</i> (%)	1 (1.4)	2 (2.7)
Minor flare, <i>n</i> (%)	11 (14.9)	11 (14.9)

13

14 **Supplemental Table 2: Estimates in a linear mixed-effects model of vaccination**
 15 **effects for SLEDAI-2K and SSC-J score in the high disease activity group (SLEDAI-**
 16 **2K>10)**

17

	Unadjusted		Adjusted	
	Estimate (95% CI)	p-value	Estimate (95% CI)	p-value
30 days (15–61 days)				
SLEDAI-2K	-0.91 (-1.16–0.66)	0.99	-0.95 (-3.13–1.23)	0.40
SSC-J	0.79 (-1.56–3.14)	0.66	0.74 (-1.63–3.11)	0.55
60 days (28–120 days)				
SLEDAI-2K	0.81 (-2.95–4.57)	0.68	0.50 (-2.32–3.32)	0.73
SSC-J	-1.42 (-4.07–1.23)	0.30	-0.61 (-3.06–1.84)	0.63
90 days (56–189 days)				
SLEDAI-2K	1.66 (1.09–2.23)	0.29	1.22 (-1.31–3.75)	0.35
SSC-J	-1.40 (-2.26–0.54)	0.44	-0.81 (-4.28–2.66)	0.65

18

19 Mixed-effects models were used to evaluate SLEDAI-2K and SSC-J scores between the
 20 groups 30 days after the second vaccination. Adjustment variables: age, sex, SLEDAI-2K
 21 and SSC-J scores at baseline, and use of immunosuppressive drugs or biological agents.
 22 CI, confidence interval; SLEDAI-2K, Systemic Lupus Erythematosus Disease Activity
 23 Index-2000; SSC-J, Japanese version of the Systemic Lupus Erythematosus Symptom
 24 Checklist Questionnaire.

25 The statistical significance level was set at $p < 0.05$.

26

27 **Supplemental Table 3: Estimated OR and 95% CI for the association between**
28 **vaccination and arthritis or arthralgia 30 days after the second vaccination**

29

	Unadjusted		Adjusted	
	OR (95% CI)	p-value	OR (95% CI)	p-value
Arthritis (SLEDAI-2K)	0.90 (0.26–3.09)	0.86	0.88 (0.20–3.85)	0.87
Arthralgia (SSC-J)	1.97 (0.74–5.29)	0.18	1.92 (0.70–5.29)	0.20

30

31 Mixed-effects logistic models were used to calculate the odds ratio and 95% CI in the
32 present study. Adjustment variables included age, sex, arthritis or arthralgia rate at
33 baseline, and use of immunosuppressive drugs or biological agents.

34 CI, confidence interval; OR, odds ratio; SLEDAI-2K, Systemic Lupus Erythematosus
35 Disease Activity Index-2000, SSC-J: Japanese version of the Systemic Lupus
36 Erythematosus Symptom Checklist Questionnaire.

37 The statistical significance level was set at $p < 0.05$.

38

39 **Supplemental Table 4: Estimates in a linear mixed-effects model of vaccination**
 40 **effects on Ph-VAS and Pt-VAS**

41

	Unadjusted		Adjusted	
	Estimate (95% CI)	p-value	Estimate (95% CI)	p-value
30 days (15–61 days)				
Ph-VAS	-0.27 (-2.60–2.06)	0.82	0.25 (-2.10–2.60)	0.84
Pt-VAS	1.35 (-1.77–4.47)	0.40	-0.98 (-4.00–2.04)	0.53
60 days (28–120 days)				
Ph-VAS	0.47 (-1.73–2.67)	0.68	-1.42 (-3.65–0.81)	0.54
Pt-VAS	-1.16 (-3.39–1.07)	0.31	0.88 (0.49–1.27)	1.00
90 days (56–189 days)				
Ph-VAS	0.34 (-2.33–3.01)	0.80	0.4 (-2.34–3.14)	0.78
Pt-VAS	-3.65 (-6.59–0.71)	0.02	-3.43 (-6.49–0.37)	0.03

42

43 Mixed-effects logistic models were used to calculate the estimate and 95% confidence
 44 interval. Adjusting factors included age, sex, Ph-VAS or Pt-VAS at baseline, and use of
 45 immunosuppressive drugs or biological agents. The missing values were adjusted using
 46 the simple imputation method to assign the mean of the values preceding and following
 47 the missing value ([Patient-VAS 0 days] n = 2; [Patient-VAS 30 days] n = 2).

48 CI, confidence interval; VAS, visual analog scale; Ph-VAS, Physician-VAS; Pt-VAS,
 49 Patient-VAS.

50 The statistical significance level was set at $p < 0.05$.

51

52 **Supplemental Table 5: Estimates in a linear mixed-effects model of vaccination**
 53 **effects for laboratory activity markers 30 days after the second vaccination**

54

	Unadjusted		Adjusted	
	Estimate (95% CI)	p-value	Estimate (95% CI)	p-value
WBC ($\times 10^3/\mu\text{L}$)	0.06 (-0.19–0.31)	0.66	0.03 (-0.36–0.42)	0.90
PLT ($\times 10^3/\mu\text{L}$)	-0.81 (-0.99–0.63)	0.99	-1.60 (-2.64–0.56)	0.003
CH50 (CH50/mL)	0.04 (-0.47–0.55)	0.87	-0.02 (-0.78–0.74)	0.96
C3 (mg/dL)	1.09 (0.17–2.01)	0.02	1.10 (-0.02–2.22)	0.05
C4 (mg/dL)	0.002 (-0.14–0.14)	0.97	0.01 (-0.42–0.44)	0.97
Anti-DNA antibody (IU/mL)	0.31 (-0.16–0.78)	0.21	0.33 (-0.16–0.82)	0.20
Protein/Creatinine ratio (g/gCr)	0.04 (0.001–0.08)	0.13	0.04 (0.001–0.08)	0.09

55

56 Mixed-effect logistic models were used to calculate the estimate and 95% confidence
 57 interval. Adjusting factors included age, sex, baseline values (including white blood cell
 58 count, platelet count, CH50, C3, C4, anti-DNA antibody titer, and urine protein/creatinine
 59 ratio), and use of immunosuppressive drugs or biological agents.

60 CI, confidence interval. WBC, white blood cells; PLT, platelet

61 The statistical significance level was set at $p < 0.05$.

62