Table 1 **Schedule of Assessments; Screening and Treatment Period (All Subjects), End of Study (Subjects Not Entering LTE Period)**

Trial Period	**Screening**	**Visit Weeks During Treatment Period**																		**Follow-Up Visit 4 weeks Post-Last Dose[a]**
Week		**0**	**2**	**4**	**6**	**8**	**10**	**12**	**14**	**16**	**20**	**24**	**28**	**32**	**36**	**40**	**44**	**48**	**52/ EOT/Early Withdrawal**	**56/ Safety Follow-Up/End of Study**
Trial Day	-28 to -1	1	15	29	43	57	71	85	99	113	141	169	197	225	253	281	309	337	365	393
Visit		Day 1	Wk 2	Wk 4	Wk 6	Wk 8	Wk 10	Wk 12	Wk 14	Wk 16	Wk 20	Wk 24	Wk 28	Wk 32	Wk 36	Wk 40	Wk 44	Wk 48	Wk 52	Wk 56
Visit window (±day)	+7	-	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	+5
Informed consent	X																			
LTE informed consent																			X	
Inclusion/exclusion criteria	X	X[b]																		
Demographics and medical history[c]	X																			
Chest X-ray[d]	X																			
12-lead ECG	X	X						X				X				X			X	X[e]
Physical examination	X	X[f]	X[g]	X[g]		X[g]		X[g]		X[g]	X[g]	X	X[h]	X[h]	X[h]	X[h]	X[h]	X[h]	X	X[g]
Vital signs, weight, height[i]	X	X[f]	X	X		X		X		X	X	X	X	X	X	X	X	X	X	X
SFI, SLEDAI-2K, PGA, BILAG 2004, CLASI	X	X[f]	X[j]	X		X		X		X	X	X	X	X	X	X	X	X	X	X
SLICC/ACR Damage Index		X[f]																	X	
C-SSRS	X			X				X			X		X		X		X		X	X

Trial Period	**Screening**	**Visit Weeks During Treatment Period**																		**Follow-Up Visit 4 weeks Post-Last Dose[a]**
Week		**0**	**2**	**4**	**6**	**8**	**10**	**12**	**14**	**16**	**20**	**24**	**28**	**32**	**36**	**40**	**44**	**48**	**52/ EOT/Early Withdrawal**	**56/ Safety Follow-Up/End of Study**
Trial Day	-28 to -1	1	15	29	43	57	71	85	99	113	141	169	197	225	253	281	309	337	365	393
Visit		Day 1	Wk 2	Wk 4	Wk 6	Wk 8	Wk 10	Wk 12	Wk 14	Wk 16	Wk 20	Wk 24	Wk 28	Wk 32	Wk 36	Wk 40	Wk 44	Wk 48	Wk 52	Wk 56
Visit window (±day)	+7	-	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	+5
IMP administration[k]		Daily administration of IMP																		
Urinalysis and microscopy	X	X[f]	X	X		X		X		X	X	X	X	X	X	X	X	X	X	X
Routine hematology, chemistry[m]	X	X[f]	X	X		X		X		X	X	X	X	X	X	X	X	X	X	X
Supplementary LFTs[n]					X		X		X											
Total Ig Levels (IgG, IgA, IgM)	X	X[f]	X	X				X				X			X				X	X
CCI																				
Coagulation (INR, PTT)	X																			
HIV[q], HCV, and HBV testing	X																			
Reflex testing for HBV DNA[r]	X			X		X		X		X	X	X			X			X	X	X
Serum pregnancy and FSH testing[s]	X																			
Serum β-D-glucan[t]	X																			
TSH	X																			

Trial Period	**Screening**	**Visit Weeks During Treatment Period**																		**Follow-Up Visit 4 weeks Post-Last Dose[a]**
Week		**0**	**2**	**4**	**6**	**8**	**10**	**12**	**14**	**16**	**20**	**24**	**28**	**32**	**36**	**40**	**44**	**48**	**52/ EOT/Early Withdrawal**	**56/ Safety Follow-Up/End of Study**
Trial Day	-28 to -1	1	15	29	43	57	71	85	99	113	141	169	197	225	253	281	309	337	365	393
Visit		Day 1	Wk 2	Wk 4	Wk 6	Wk 8	Wk 10	Wk 12	Wk 14	Wk 16	Wk 20	Wk 24	Wk 28	Wk 32	Wk 36	Wk 40	Wk 44	Wk 48	Wk 52	Wk 56
Visit window (±day)	+7	-	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	+5
Tuberculosis assessment[l]	X																			
Urine pregnancy test[s]		X[f]	X	X		X		X		X	X	X	X	X	X	X	X	X	X	X
UPCR	X	X[f]	X	X		X		X		X	X	X	X	X	X	X	X	X	X	X
SF-36v2, LupusQoL, FACIT-Fatigue, EQ-5D-5L[u]		X		X		X		X		X		X		X		X			X	X
HRU				X		X		X		X	X	X	X	X	X	X	X	X	X	X
PGIC[u]				X		X		X		X		X		X		X			X	X
Dispense IMP		X	Dispense as needed, using IWRS																	
Dispense subject diary		X	Dispense as needed.																	
Concomitant medications / procedures	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Adverse Events	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
CCI [redacted]																				

Trial Period	**Screening**	**Visit Weeks During Treatment Period**																		**Follow-Up Visit 4 weeks Post-Last Dose[a]**
Week		**0**	**2**	**4**	**6**	**8**	**10**	**12**	**14**	**16**	**20**	**24**	**28**	**32**	**36**	**40**	**44**	**48**	**52/ EOT/Early Withdrawal**	**56/ Safety Follow-Up/End of Study**
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Visit		Day 1	Wk 2	Wk 4	Wk 6	Wk 8	Wk 10	Wk 12	Wk 14	Wk 16	Wk 20	Wk 24	Wk 28	Wk 32	Wk 36	Wk 40	Wk 44	Wk 48	Wk 52	Wk 56
Visit window (±day)	+7	-	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	+5
Immunological Assessments																				
Anti-dsDNA, Complement (C3, C4), CRP	X	X[f]		X		X		X		X	X	X	X	X	X	X	X	X	X	X
ANA, anti-Sm	X																			
Autoantibodies		X										X							X	X
Exploratory Biomarkers																				
CCI [redacted]																				

Trial Period	Screening	Visit Weeks During Treatment Period																		Follow-Up Visit 4 weeks Post-Last Dose[a]
Week		**0**	**2**	**4**	**6**	**8**	**10**	**12**	**14**	**16**	**20**	**24**	**28**	**32**	**36**	**40**	**44**	**48**	**52/ EOT/Early Withdrawal**	**56/ Safety Follow-Up/End of Study**
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Visit		Day 1	Wk 2	Wk 4	Wk 6	Wk 8	Wk 10	Wk 12	Wk 14	Wk 16	Wk 20	Wk 24	Wk 28	Wk 32	Wk 36	Wk 40	Wk 44	Wk 48	Wk 52	Wk 56
Visit window (±day)	+7	-	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	+5
CCI [redacted]																				

ACR = American College of Rheumatology, ALT = alanine aminotransferase, ANA = Antinuclear Antibody(ies), Anti-dsDNA = Anti-Double-Stranded Deoxyribonucleic Acid, Anti-Sm = anti-Smith antibody, AST = aspartate aminotransferase, BILAG = British Isles Lupus Assessment Group, BP = blood pressure, CCI [redacted], CLASI = Cutaneous Lupus Erythematosus Disease Area and Severity Index, CRP = C-Reactive Protein, C-SSRS = Columbia-Suicide Severity Rating Scale, DNA = deoxyribonucleic acid, ECG = Electrocardiogram, EOT = End of Treatment, EQ-5D-5L = EuroQoL 5 Dimension 5 Levels, FACIT = Functional Assessment of Chronic Illness Therapy, GGT = γ-Glutamyl-transferase, Ig = Immunoglobulin, IMP = Investigational Medicinal Product, IWRS = Interactive Web Response System, HBV = Hepatitis B Virus, HCV = Hepatitis C Virus, HIV = Human Immunodeficiency Virus, HRQoL = Health Related Quality of Life, HRU = Health Resource Utilization, INR = International Normalized Ratio, LFT = liver function test, LTE = long-term extension, LupusQoL = Lupus Quality of Life, mRNA = messenger Ribonucleic Acid, CCI [redacted] PCR = polymerase chain reaction, PGA = Physician's Global Assessment, PGIC = Patient Global Impression of Change, CCI [redacted], PTT = Partial Thromboplastin Time, SF-36v2 = Medical Outcomes Study 36-Item Short Form Health Survey, SFI = SLEDAI Flare Index, SLEDAI-2K = Systemic Lupus Erythematosus Disease Activity Index-2000, SLICC = Systemic Lupus International Collaborating Clinics, TB = tuberculosis, TSH = Thyroid Stimulating Hormone, UPCR = Urine Protein To Creatinine Ratio, Wk = Week.

a Safety Follow-Up Visit will be conducted at four weeks after the last dose of IMP for subjects who have been discontinued from IMP or have completed the 52-week Treatment Period, unless subjects have entered the LTE period.

b Subject eligibility to be confirmed on Day 1 prior to randomization.

c Medical history includes documentation of SLE classification criteria, SLE medical history, medications, and surgery/procedures (see Section 7.2.1).

d The results of a chest X-ray performed within three months prior to the Screening Visit (if available) are acceptable, provided there is no reason to suspect any clinical changes, per Investigator discretion.

e Only required if change noted at Wk52/EOT, when compared to Baseline ECG.

f Predose sample/procedure to be collected/performed before the first daily dose.

g Abbreviated physical examination at these visits (see Section 7.4.4.2).

h Abbreviated physical examination may be performed at Primary Investigator discretion, as required to fully obtain information needed for the BILAG and/or SLEDAI assessments, if scheduled, as well as required to fully evaluate any subject complaints or adverse events.

i Vital signs include arterial BP, pulse rate, respiratory rate, and body temperature. Height will be measured at Screening only. Body weight will be measured with a balance beam scale, if possible. Pulse rate and BP will be measured after 10 minutes rest in the semisupine position with the subject's arm unconstrained by clothing or other material. The BP should be assessed on the same arm for each subject throughout the study.

j Only CLASI assessed at Week 2.

k On Study Visit Days, IMP should be administered during the Study Visit; otherwise, IMP should be self-administered at home at a set time each day (every 12 hours ± 2 hours). Investigational medicinal product administration at Week 52 will only occur for subjects rolling over into the LTE.

l A Quantiferon test will be performed centrally. Prior TB testing results must be entered into the eCRF.

m See Table 11 for list of clinical laboratory evaluations.

n Supplementary LFTs include AST, ALT, alkaline phosphatase, GGT, and bilirubin.

C [redacted]
C

p To be collected at Screening only in subjects who have previously received B cell depleting therapy (see Exclusion Criterion 33, in Section 5.3.2).

q HIV testing will be performed locally.

r For subjects who are negative for hepatitis B surface antigen (HBsAg) but are anti-hepatitis B surface antibody positive and/or anti-hepatitis B core antibody positive, an HBV DNA PCR reflex test is to be completed at screening. If the subject enters the study with positive HBV DNA negative OR has detectable HBV DNA < 20 IU/mL only, additional HBV DNA PCR testing must be performed (see Exclusion criteria 20, in Section 5.3.2).

s For women of childbearing potential or who are postmenopausal see inclusion criterion 7. A follicle-stimulating hormone (FSH) must be drawn at Screening if necessary to confirm postmenopausal status. The urine pregnancy test being used at all time points in this study must be a highly sensitive urine pregnancy test.

t For Japan only.

u HRQoL Questionnaires should be completed before any other procedures are performed.

CCI [redacted]