2021-000962-14 primary and secondary endpoints

	Baseline median (IQR)	Week 12 median (95% CI)	Change at Week 12 from Baseline median (95% CI)	Week 36 median (95% CI)	Change at Week 36 from Baseline median (95% CI)
Primary endpoint					
Anti-dsDNA antibodies (IU/ml)	166.3 (87.3 – 351.0)	61.1 (40.0 – 106.6)	−109.6 (−274.5 – −38.1)	80.4 (27.8 – 127.2)	−123.0 (−236.4 – −34.2)
Clinical secondary endpoints					
SLEDAI-2K	12 (10–14)	4 (2 – 4)	-8 (-10 – -6)	4 (2 – 10)	-9 (-10 – -2)
cSLEDAI-2K	11 (8–12)	2 (0 – 4)	-8 (-10 – -6)	1 (0 – 2)	-10 (-14 – -10)
PGA (0-3)	2.2 (2.1– 2.2)	0.2 (0.1 – 0.3)	-2.0 (-2.1 – -1.8)	0.3 (0.1 – 0.7)	-1.8 (-2.0 – -1.4)
SRI-4 response (%)	-	100 (10/10)		70 (7/10)	
LLDAS rate (%)	-	50 (5/10)		60 (6/10)	
Remission rate (%)	-	20 (2/10)		50 (5/10)	
CLASI	6.0 (3.0– 6.0)	0.0 (0.0– 0.0)	-5.0 (-6.0 – -3.0)	0.5 (0.0 – 3.0)	-4.0 (-6.0 – -1.0)
CDAI	11.5 (4.0– 13.5)	0.0 (0.0–1.0)	-11.0 (-13.5– -4.0)	1.0 (0.0 – 4.0)	-9.5 (-11.0– -4.0)
UPCR (mg/g Creatinine)[1]	649 (272– 1604)	302 (117–768)	-269 (-690 – -84)	325 (271 – 371)	-351 (-1261– -19)
Prednisolone dosage (mg/d)	6.25 (5–9)	6.25 (5–9)	0 (0–0)	5.0 (4–5)	-2.75 (-3.5–0)
SFI flare rate (%)	-	0 (0/10)		20 (2/10)	
Serologic secondary endpoints					
C3 (mg/l)	875 (690– 940)	955 (810 – 1140)	130 (80–230)	1,045 (810 – 1,070)	105 (-30 – 180)
C4 (mg/l)	145 (100– 150)	165 (130– 210)	40 (30 – 60)	125 (110 – 190)	30 (-20 – 50)
IgG[2] (g/l)	12.1 (8.9 – 19.9)	6.9 (5.9 – 11.3)	−6.9 (−8.4 – −3.2)	9.5 (6.0 – 14.1)	−3.0 (−4.4 – −2.0)
IgM[2] (g/l)	0.6 (0.3– 0.9)	0.2 (0.1– 0.4)	-0.2 (-0.5– -0.1)	0.3 (0.2 – 0.7)	-0.1 (-0.2–0.0)
IgA[2] (g/l)	2.3 (1.5– 2.9)	0.6 (0.5– 0.8)	-1.5 (-2.0– -1.1)	0.7 (0.6 – 1.3)	-1.0 (-1.6– −0.6)
Antinuclear antibody (reciprocal titres)	640 (640– 5120)	320 (320– 2560)	-320 (-320– -320)	640 (160 – 2,560)	-400 (-480– -320)
Anti-SSA[3] (IU/ml)	199.4 (78.3 – 201.9)	134.3 (26.3– 185.7)	-20.3 (-67.6– -18.7)	95.8 (46.4 – 188.8)	-16.9 (-70.3– -10.7)
Anti-RNP[4] (IU/ml)	197.5 (59.5 – 354.5)	169.4 (8.3–303.6)	-45.0 (-56.1– -18.9)	190.7 (29.2– 316.8)	-31.0 (-50.2– -5.6)
Anti-Sm[5] (UI/ml)	159.2 (72.8 – 245.6)	96.3 (19.6–173.0)	−62.9 (-72.7– -53.2)	110.7 (13.5–208.0)	-48.5 (-59.3– -37.6)

Reduction of anti-dsDNA antibodies during the treatment with daratumumab and dexamethasone was accompanied by a rapid and marked clinical improvement in all patients with a significant reduction oftheSLEDAI-2Kscorefromamedian12atbaselineto4atweek12 (median difference:-8,95%CI:-6–-10),which remained stable until the final study visit at week 36.

Immunoglobulin G (IgG) levels significantly declined at week 12 (median difference-6.9g/dl, 95% CI:-8.4–-3.2), with values dropping below 5g/l in five patients.

Remission according to DORIS (Definition Of Remission In SLE) criteria29,defined as having a clinical SLEDAI-2Kof0, a Physician's Global Assessment (PGA) < 0.5 and prednisolone≤5mg/day, was achieved in 50% of participants atthefinalstudyvisit.Twodiseaseflares occurred at week 20 andweek24,definedasatleast1newSLEDAI-2Kmild/moderateor severe flare compared with baseline as assessed using the SELENA SLEDAI flare index (SFI). Flares developed in patients #3 and #4 with symptomssimilarto those prior to treatment, including joint and skin manifestations, resulting in the initiation of belimumab therapy