Abstract 1122 Table 1 Comparison of Effect Sizes for TB vs Placebo groups between LuMOS and SRI-5

Trial	Group (n)	LuMOS: Effect Size (95% CI)	SRI-5: Effect Size (95% CI)
ILLUMINATE-1	TB-q4weeks (n=378)	0.44 (0.30; 0.59)	0.13 (- 0.02; + 0.27)
ILLUMINATE-1	TB-q2weeks (n=381)	0.42 (0.27; 0.56)	0.05 (- 0.09; + 0.20)
ILLUMINATE-2	TB-q4weeks (n=376)	0.54 (0.39; 0.68)	0.15 (+0.01; +0.30)
ILLUMINATE-2	TB-q2weeks (n=372)	0.69 (0.53; 0.83)	0.23 (+0.08; +0.37)

treatment groups *versus* placebo, and compared it with SRI-5 responder index used in the original trials.

Results LuMOS using standardized z-score transformed laboratory data worked comparably to the original LuMOS model in the analyses of original belimumab trials and was then applied to the Illuminate data sets. LuMOS-based ES for both TB groups in both trials indicated highly significant ($p < 0.0001$), moderately strong treatment effects ($ES > 0.4$), in contrast to weak effects ($ES < 0.25$) based on SRI-5, that were statistically *non-significant* for Illuminate-1, as reflected by the 95% CI's that included 0 (table 1).

Conclusion LuMOS improves the ability to detect statistically significant treatment effects. Further validation in SLE trials of non-B cell directed treatments is necessary to document utility as an outcome measure independent of drug mechanism.

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REFERENCE

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1123

REMISSION AND LUPUS LOW DISEASE ACTIVITY STATE (LLDAS) ARE ASSOCIATED WITH A LOWER PROBABILITY OF FLARES IN SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) PATIENTS. DATA FROM THE ALMENARA LUPUS COHORT

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Background Remission and LLDAS have been proposed as the treatment goal for SLE patients. Different investigators have reported that achieving these states prevent damage accrual; however, their independent impact on the occurrence of flares has been only scarcely evaluated. The aim of this study was to evaluate the independent impact of remission and LLDAS on flares.

Abstract 1123 Table 1 Factors associated with flares. Univariable and multivariable models

	OR (95%CI)	p value	OR (95%CI)	p value
Disease activity state				
Active	Ref.		Ref.	
LLDAS	0.405 (0.182-0.903)	0.027	0.358 (0.152-0.841)	0.018
Remission	0.604 (0.400-0.912)	0.017	0.595 (0.387-0.916)	0.018
Age at diagnosis, years	1.001 (0.987-1.016)	0.846	1.002 (0.986-1.180)	0.791
Female gender	1.234 (0.482-3.159)	0.661	1.379 (0.564-3.373)	0.481
SES				
Low	Ref.		Ref.	
Medium	1.212 (0.788-1.863)	0.382	1.140 (0.672-1.935)	0.627
High	0.935 (0.488-1.792)	0.839	0.792 (0.276-2.274)	0.665
Educational level, years	0.989 (0.919-1.063)	0.756	0.977 (0.861-1.109)	0.722
Disease duration	0.989 (0.963-1.017)	0.443	0.988 (0.956-1.021)	0.469
SDI	1.044 (0.929-1.173)	0.468	1.047 (0.928-1.180)	0.456
Antimalarial use				
Current	Ref.		Ref.	
Past	1.027 (0.553-1.908)	0.933	1.076 (0.578-2.003)	0.558
Never	1.287 (0.285-5.808)	0.743	1.533 (0.367-6.400)	0.818

OR: Odds ratio. LLDAS: Lupus low disease activity state. SES: Socioeconomic status. SDI: SLICC/ACR damage index.

Methods SLE patients from a single center cohort with at least two visits were included. Visits were performed every six months. Disease activity state was defined as three independent states: remission defined as a SLEDAI-2k (excluding serology) = 0, physician global assessment (PGA) < 0.5, prednisone daily dose ≤ 5 mg/d and immunosuppressive drugs on maintenance dose (based on 2021 DORIS definition); LLDAS defined as a SLEDAI-2k ≤ 4 with no activity in major organ systems, with no new features of lupus disease activity compared to the previous assessment, physician global assessment (PGA) ≤ 1.0, prednisone daily dose ≤ 7.5 mg/d; and the rest were defined as active. Flares were defined as an increase of at least four points in the SLEDAI-2k between two consecutive visits. Generalized estimating equations were performed, using as outcome the occurrence of a flare in the subsequent visit, and the activity state in the previous visit; multivariable models were adjusted for possible confounders [age, gender, socioeconomic status, educational level, disease duration, antimalarial use and SLICC/ACR damage index (SDI)]. All the confounders were measured in the same visit than the activity state.

Results Two hundred and eighty-one patients were included, they were followed-up for 2.7 (1.1) years. A total of 1346 visits were included, 730 (54.2%) of them were on remission, 190 (14.1%) were on LLDAS, and 426 (31.6%) were active. One hundred and one flares occurred during the follow-up among these 281 patients; 197 of them (70.1%) did not present flares, 67 (23.8%) presented one flare and 17 (6.0%) presented two flares. Remission and LLDAS were associated with a lower probability of flares. Univariable and multivariable models are depicted in table 1.

Conclusions Remission and LLDAS are independently associated with a lower probability of flares. These results reinforce the importance of these states as the goals of SLE treatment.