Baseline normal/high C3*				
N	28	33	314	301
Response, n (%)	14 (50.0)	21 (63.6)	139 (44.3)	152 (50.5)
Difference, BEL vs PBO,%		13.64		6.23
OR (95% CI)		1.75 (0.63, 4.88)		1.31 (0.94, 1.82)
Baseline low C4*‡				
N	14	21	303	327
Response, n (%)	5 (35.7)	8 (38.1)	98 (32.3)	166 (50.8)
Difference, BEL vs PBO,%		2.38		18.42
OR (95% CI)		1.11 (0.27, 4.51)		2.45 (1.74, 3.45)
Baseline normal/high C4*				
N	25	32	259	236
Response, n (%)	12 (48.0)	20 (62.5)	120 (46.3)	119 (50.4)
Difference, BEL vs PBO,%		14.50		4.09
OR (95% CI)		1.81 (0.62, 5.22)		1.19 (0.82, 1.72)
Baseline steroids*				
Yes				
N	37	50	488	478
Response, n (%)	17 (45.9)	28 (56.0)	189 (38.7)	254 (53.1)
Difference, BEL vs PBO,%		10.05		14.41
OR (95% CI)		1.50 (0.64, 3.52)		1.86 (1.42, 2.42)
No				
N	2	3	74	85
Response, n (%)	0 (0)	0 (0)	29 (39.2)	31 (36.5)
Difference, BEL vs PBO,%		0		-2.72
OR (95% CI)		–		0.91 (0.47, 1.76)

Post hoc analyses; †Low C3 defined as <90 mg/dL; ‡low C4 defined as <10 mg/dL
BEL, belimumab; C, complement; CI, confidence interval; OR, odds ratio; PBO, placebo

placebo, plus SoC (BLISS trials).[3] The primary endpoint was SLE Responder Index 4 (SRI4) at Week 52. This *post hoc* across-trial comparison (intention-to-treat [ITT] population) investigated the treatment effect of belimumab according to baseline disease activity indicators (Safety of Estrogens in Lupus Erythematosus National Assessment-SLE Disease Activity Index [SELENA-SLEDAI] score, anti-dsDNA and complement C3/C4 levels) and steroid use; analyses were descriptive.

Results In PLUTO, belimumab demonstrated higher SRI4 response versus placebo; this response was similar for patients with baseline SELENA-SLEDAI scores of ≥10 and ≤9, and for and those receiving steroids, but greater in those with scores ≥13, low anti-dsDNA, or normal/high C3/C4 (**table 1**). Subgroup analyses from the BLISS adult studies demonstrated similar findings with the exception of patients with high anti-dsDNA or low C3/C4 (**table 1**).

Conclusions Subgroup analyses from the PLUTO trial demonstrated favourable belimumab responses in paediatric patients with high SELENA-SLEDAI scores, similar to those observed in adult belimumab studies. However, these results should be interpreted with caution due to the small sample size of PLUTO, the post hoc nature of the analyses and other limitations.

Disclosures DLB, MO, AH, BJ, DR and HQ are employees of GSK. BJ and DLB hold stocks and shares in GSK; MO, AH, DR and HQ hold shares in GSK.

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P129 ADOPTIVE TRANSFER OF AUTOLOGOUS CYTOTOXIC T LYMPHOCYTES AGAINST EPSTEIN-BARR VIRUS (EBV-CTL) IN PATIENTS WITH SYSTEMIC LUPUS (SLE): PRELIMINARY RESULTS

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Background Patients with SLE show insufficient EBV control with an increased viral load and a decreased cytotoxic T-cell response associated with an abnormal humoral responses which theoretically may be pathogenic. In the present study we proposed an adoptive transfer of EBV-CTL to try to restore patients EBV specific T-cell control, and assess its effect on the humoral responses and the clinical status.

Methods Nine patients with SLE were enrolled in a Phase I/II clinical trial to receive autologous EBV-CTL (5.10^6 cells/kg). The frequency of EBV-specific T cells before and 10 days after injection was evaluated i) by ELISPOT directly on the peripheral blood mononuclear cells and ii) by estimation of IFN-γ, IL-2, TNF-α production and CD107 expression after pre-amplification of the EBV-specific precursors in vitro. We also monitored anti-VCA, anti-EAD, and anti-EBNA antibodies titers, EBV viral load, and clinical and biological disease activity parameters.

Results To date, 6 patients received EBV-CTL treatment. Ten days after injection, the EBV-CTL frequencies observed by ELISPOT increased moderately for 2 out of 3 patients tested. On the pre-amplified cells, increase in the production of IFN-γ after BLCL stimulation was observed for 4 out of 6 patients, and in the CD107 expression for 3 out of 6 patients. Serology titers remained stable during follow-up, with the exception of the anti-EBNA and anti-VCA IgG titers, which decreased in one patient. The viral EBV blood load did not vary significantly.

Conclusions The administration of EBV-CTL seems safe and well tolerated in SLE patients. Yet it might not be sufficient to improve the control of the virus by the host (and modify humoral response against EBV) despite a discreet increase in the EBV specific T-cell repertoire after injection. More data still need to be collected to precise the effects of the treatment on anti-EBV response and disease activity.