prednisone-equivalent ≤7.5 mg/day, and stable maintenance doses of immunosuppressants). A pre-defined subset of patients was also evaluated, with high disease activity (HDA: SLEDAI-2K≥10 at Screening). Differences in clinical response between patients treated with atacicept and PBO at Week 24 were analysed using odds ratio estimated from logistic regression.

Results The ITT population included 306 patients, and 158 had HDA. There was a trend towards improved SRI-4 response with atacicept vs PBO at Week 24 (p=ns in primary analysis; screening visit as baseline, BL). In a pre-specified sensitivity analysis using study day 1 as BL, a significantly larger proportion of patients on atacicept achieved SRI-4 response at week 24. In the HDA subpopulation, there were significant improvements in SRI-4,–5, −6,–7 and −8 response rates and attainment of LDA with atacicept 150 mg vs PBO (table 1). Atacicept was associated with increased serum C3 and C4, and decreased IgG, IgA, IgM and anti-dsDNA antibodies over time. Rates of treatment emergent adverse event (TEAE) and serious TEAEs were similar among groups. The most frequent serious TEAEs were infections but the incidence was not increased in the atacicept groups vs PBO.

Conclusions Atacicept showed evidence of efficacy in SLE with a dose-dependent reduction of SLE disease activity in patients with HDA. Atacicept was associated with an acceptable safety profile. These results also suggest that more discriminatory endpoints will be useful for future SLE clinical trials.

S7A:6 BASELINE SERUM LEVELS OF BAFF OR APRIL ARE INDEPENDENT PREDICTORS OF SLEDAI RESPONSE AFTER 12 MONTHS OF TREATMENT WITH BELIMUMAB IN PATIENTS WITH REFRACTORY SYSTEMIC LUPUS ERYTHEMATOSUS

[1]S Piantoni, [1]L Andreoli, [2]T Lowin, [1]R Kumar, [1]F Regola, [1]P Airò, [1]F Franceschini, [1]A Tincani, [2]G Pongratz. *[1]Rheumatology and Clinical Immunology, Spedali Civili and University of Brescia, Italy; [2]Rheumatology Department and Hiller Research Centre for Rheumatology, University Hospital Düsseldorf, Germany*

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Background Belimumab, a monoclonal antibody targeting BlyS (B lymphocyte stimulator), is used in refractory Systemic Lupus Erythematosus (SLE). Pivotal clinical trials showed that SLE patients with positive anti-dsDNA antibodies and reduced levels of C3 and/or C4 fractions were those more likely to be responders to treatment. Our study aims at exploring predictors of response to Belimumab in the post-marketing experience in consecutive SLE patients treated at a single centre.

Methods Twenty-one patients received Belimumab intravenously at standard regimen (10 mg/kg at 0–15–30 days and then every 4 weeks). Anti-dsDNA were tested by Farr assay and C3/C4 levels by nephelometry. Biomarkers belonging to the TNF superfamily and related to B cell activity (BAFF, APRIL, sBCMA, sCD40L, sTACI, TWEAK) were tested by ELISA. All laboratory parameters were tested at baseline and every 6 months afterwards. SLE disease activity was assessed by SLEDAI-2K score. General linear modelling and correlation analysis were performed using SPSS.

Results Enrolled patients were 2 males and 19 females with a median (25th-75th percentile) age of 38 (31–42) years. The disease duration at time of Belimumab start was 12 (8–19) years. The baseline SLEDAI score was 6 (4–9), the anti-dsDNA level was 26 (11–99) UI/ml, and their C3 and C4 level was 72 (56–86) and 9 (7–15) mg/dL, respectively.

All the parameters of the TNF superfamily showed moderate/strong correlation (r values ranging from 0.543 and 0.989, p<0.01). With and without correction for different variables, BAFF and APRIL serum levels measured at the start of Belimumab treatment were the most robust predictors of relative SLEDAI reduction after 12 months of treatment (table 1).

In contrast, C3, C4, anti-dsDNA, and SLEDAI were less likely to predict relative SLEDAI change at 12 month of Belimumab treatment (uncontrolled model: C3 p=0.410; C4 p=0.778; anti-dsDNA p=0.412) in this cohort of patients preselected for the treatment with Belimumab.

Conclusions In this preselected 'real-life' cohort of refractory SLE patients fulfilling the requirements for Belimumab treatment baseline serum levels of BAFF or APRIL are independent predictors of response to treatment. Therefore, BAFF and APRIL could be useful for response estimation in patients qualifying for Belimumab treatment.

Abstract S7A:6 Table 1 General linear modelling to calculate predictive value of baseline BAFF and APRIL levels for the relative change of SLEDAI at 12 month

General linear modeling (GLM), ANOVA	Baseline APRIL as predictor of SLEDAI change at 12 month BELIMUMAB	Baseline BAFF as predictor of SLEDAI change at 12 month BELIMUMAB
uncontrolled	F= 8.289; p < 0.001	F= 8.195; p < 0.001
controlled for initial AGE, LEUCOCYTES, CRP	F= 7.272; p = 0.007	F= 7.647; p = 0.006
controlled for initial AGE, LEUCOCYTES, CRP, SLEDAI	F= 5.929; p = 0.019	F= 6.624; p = 0.015

S7A:7 ADMINISTRATION OF SERPINB3 DELAYS GLOMERULONEPHRITIS AND ATTENUATES THE LUPUS-LIKE DISEASE IN LUPUS MURINE MODELS BY AN IMMUNOMODULATORY EFFECT

[1]M Gatto, [2]L Cavicchioli, [1]R Luisetto, [3]G Codolo, [1]G Maggioni, [1]F Saccon, [1]M Beggio, [4]P Pontisso, [1]A Ghirardello, [1]A Doria. *[1]University of Padova – Unit of Rheumatology, Department of Medicine, Padova, Italy; [2]University of Padova – Department of Biomedicine and Nutrition, Padova, Italy; [3]University of Padova – General Pathology Unit, Department of Biology, Padova, Italy; [4]University of Padova – Department of Clinical and Experimental Medicine, Padova, Italy*

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Background Abnormal apoptosis and clearance of cellular debris concur to development of systemic lupus erythematosus (SLE). SERPINS (serin-protease inhibitors) are ancient molecules regulating immune homeostasis. SERPINB3 modulates apoptosis and is hypoexpressed on SLE B cells.

Aim To explore the effects of SERPINB3 administration in murine lupus models, focusing on glomerulonephritis.