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Background: Lupus nephritis (LN) is one of the most severe manifestations in systemic lupus erythematosus (SLE), constituting a substantial cause of end-stage kidney disease, dialysis, and mortality. Prompt and adequate treatment of LN, and prevention of renal flares are key components of disease management towards improved outcomes in patients with SLE.

Objectives: We aimed to determine the effect of the use of antimalarial agents (AMA) and different doses and pharmaceutical forms of belimumab on preventing renal flares in patients with active SLE.

Methods: We pooled data from the BLISS-52, BLISS-76, BLISS-SC and BLISS-Northeast Asia randomised clinical trials of belimumab (N=3225), that included patients with seropositive (antinuclear antibody titres ≥1:80) and antiphospholipid antibodies (aPL) with lupus anticoagulant (LAC) and different doses and pharmaceutical forms of belimumab on prevent-

Results: In total, 192 patients developed a renal flare after a median of 197 days. In multivariable Cox regression analysis, use of AMA was associated with a lower risk of renal flares (HR: 0.64; 95% CI: 0.54–0.96; p=0.026). Compared with placebo, the risk of renal flares was lower among patients receiving IV belimumab 1 mg/kg (HR: 0.44; 95% CI: 0.25–0.79; p=0.006) and IV belimumab 10 mg/kg (HR: 0.27; 95% CI: 0.13–0.70; p=0.005) and patients receiving IV belimumab 10 mg/kg (OR: 0.45; 95% CI: 0.27–0.75; p=0.002) were protected against renal flares only when belimumab use was combined with AMA.

Conclusion: In this RCT setting, belimumab and AMA protected against renal flares in patients with active seropositive SLE yet no ongoing severe renal involve-

ment. The protective effect of IV belimumab against renal flares appeared optimal when belimumab was combined with AMA. The prominent effect of low-dose beli-

numab motivates investigation of the efficacy of intermediate doses of belimumab. Acknowledgements: The authors would like to thank GlaxoSmithKline for pro-

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[1] Furie R et al - Anifrolumab, an Anti-Interferon-α Receptor Monoclonal Antibody, in Moderate-to-Severe Systemic Lupus Erythematosus, Arthritis Rheu-
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AB0540 COAGULATION AND HAEMOSTASIS PARAMETERS IN PREGNANT WOMEN WITH SYSTEMIC LUPUS ERYTHEMATOSUS AND HEALTHY CONTROLS WITH AND WITHOUT PREECLAMPSIA

Keywords: Pregnancy and reproduction, Systemic lupus erythematosus

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Background: Women living with Systemic Lupus Erythematosus (SLE) are at increased risk of pregnancy complications, including preecclampsia (PE). Placental dysfunction is the key pathogenic event, but the underlying mechanisms are scarcely known.

Objectives: This study aimed to investigate global hemostatic assays in pregnant SLE patients in relation to PE and the use of anti-thrombotic prophylaxis.

Methods: Patients with SLE were sampled during the third trimester of gestation for coagulation and haemostasis (C&H) assays: 1) overall coagulation potential (OCP); 2) overall haemostatic potential (OHP); 3) overall fibrinolytic potential (OFP), plasma levels of fibrinogen and D-dimer. Pregnant healthy controls (HC) with and without PE were also analysed.

Results: Twenty-two consecutive pregnant SLE patients, 80 pregnant HC without PE, and 42 pregnant HC with PE were analysed. Disease characteristics, pregnancy features, and coagulation parameters are reported in Table 1. No thrombotic or bleeding events occurred in SLE patients. Four SLE patients experienced PE (18.2%) despite treatment with low dose acetylsalicylic acid (LDASA) a low molecular weight heparin (LMWH). These patients displayed significantly lower OCP and OFP, but not OHP, as compared to SLE without PE. Among 4 SLE+PE patients, the 2 treated with LMWH tended to have lower OCP, OHP, and OFP values as compared to the 2 untreated patients (134.9±190.7 vs 372.3±24.6; 90.6±128.2 vs 202.2±24.1; 16.4±23.3 vs 45.4±10.1). Among SLE patients treated with LMWH, undetectable

AB0539 ANIFROLUMAB FOR REFRACTORY SKIN DISEASE IN SYSTEMIC LUPUS ERYTHEMATOSUS (SLE): A SINGLE CENTER CASE SERIES

Keywords: Systemic lupus erythematosus, Skin, bDMARD

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Background: Anifrolumab (AN) a human monoclonal antibody to type I interferon receptor subunit 1 has been recently approved for the treatment of SLE. In SLE, the skin is not only a target but also a key- driver of the autoimmune response via the production of type I IFN.

Objectives: To evaluate the efficacy of AN in real-life under the early access program (09/2021 – 03/2022).

Methods: A total of seven patients (all female, mean age 50 years, disease duration 15 years) with SLE (diagnosis based on ACR1997 or SLICC or EULAR/ACR 2019 classification criteria for SLE and inadequate response to prior immunosuppressive therapies) received AN from 09/2021 until 03/2022 as part of an early access program. Patients’ demographics, clinical and laboratory characteristics, disease activity (SLEDAI-2K, CLASI) were recorded at baseline and first months of the administration of AN.

Results: Active skin disease was the dominant clinical manifestation of all patients for the administration of AN (subacute cutaneous lupus in 6/7, discoid lupus in 3/7, severe chelumellar lesions in one patient). Patients had received an average of 5.1 immunosuppressive drugs before AN, with an inadequate response. The mean (SD) SLEDAI index at baseline was 6.9 (1.1) and the mean (SD) prednisone dose 2.7 (2.8) mg/day. In reference to the skin disease, mean (SD) CLASI (Activity/Dam-
age) before first administration of AN was 9.9±4.6 (6.3/2.2). A rapid response of the skin disease, especially the subacute cutaneous lupus lesions, was observed from the first injection of AN. As expected, the results were less prominent in patients who had discoid lupus lesions, although patients reported subjective improvement. The mean (SD) SLEDAI, CLASI and daily prednisone dose are 3.4 (1.8), 3.1 (1.4)/2.2) and 2.5 (2.5) mg, respectively. After a mean (SD) follow-up of 5.7 (2.0) months, one patient discontinued AN due to VZV infection.

Conclusion: IFN inhibition is effective for the treatment of refractory cutaneous lupus manifestations. The prompt response of the dermatologic disease to AN likely reflects the beneficial effects of neutralization of IFN on the autoimmune and vasculopathic processes in SLE.

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