as a therapeutic option in this context decades ago and evidence of its benefit in the context of fibrosis in various conditions, including LN, is ever-increasing. Despite these facts, BMP-7 is not being implemented as therapy in the context of renal disease. Our objective was to understand the hurdles to implementation of this promising therapeutic modality.

Methods A comprehensive review of the peer-reviewed (rheumatic and non-rheumatic) literature on BMP-7 was conducted to identify potential physiological risks which may preclude implementation of BMP-7 as treatment in the context of LN. In addition, information on commercial BMP-7 drug development initiatives was collated, to assess potential economic reasons for lack of BMP-7-based pharmaceuticals. Finally, we conducted a general search of literature to find potential solutions to the high cost of clinical trials in general, to enable recommendations on ways in which to increase feasibility of BMP-7 clinical trials.

Results From a large body of literature consulted, no significant risk of adverse outcome could be identified for BMP-7. In the context of pharmaceutical manufacturing itself, high production cost was identified as a potential limiting factor. The choice of primary disease focus in initial clinical trials seem to be another significant indicator of early failure of a potential drug, as well as the generally high cost of clinical trials.

Conclusion We concluded that modern technology should be integrated into modern medicine as a priority to increase drug development success rate and propose a bench-to-bedside pipeline by which this may be achieved.

P99 HISTOLOGICAL RENAL FEATURES AND CYTOKINES ASSESSMENT AS POSSIBLE BIOMARKERS IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS AND LUPUS NEPHRITIS

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Background The study aim is to identify a multipanel biomarkers matrix, to improve stratification and management of lupus nephritis (LN).

Methods 45 SLE-patients (age:40.5 ± 11.0) at disease onset/flare were enrolled. 28 patients with LN underwent renal biopsy, classified according to ISN/RPS and to the BANFF-score for active interstitial infiltrate (II). 15 patients had non-renal-SLE (NR-SLE). Laboratory, immunological and disease-activity data were collected at baseline and then at 6(T6) and 12(T12) months. Serum level of BAFF, IL-2, IL-6, IL-17 and IFN-alpha were assayed by ELLA-panel at each timepoint.

Results Considering LN-patients, 66% had class III/IV, 71.8% had II>5%. Performing univariate analysis for each renal outcome, focusing on histology, a significant association between higher activity index and worse prognosis in terms of remission at T12 (p= 0,04), proteinuria and renal damage development (p= 0,04 and p= 0,03 respectively) was observed. Furthermore LN patients with II>5% were less likely to achieve early remission (p= 0,04) together with those with antiphospholipid antibody (ApL) positivity (p= 0,05).

The analysis of cytokines revealed that serum levels of IL-6 were significantly higher in SLE active patients as compared to controls (LN vs R-LN, p=0.02; NR-SLE vs R-LN, p=0.02), whereas IFN-alpha levels were significantly increased only in LN patients (LN vs R-LN, p=0.01).

Serum levels of IL-6 in LN patients positively correlated with disease activity index (R=0.819; p<0.001), negatively with C3 (R= -0.608; p=0.003) and C4 (R= -0.675; p=0.01) and they were associated with histological severity, being significantly higher in patients with II>5% (p= 0.01) and positively correlating with activity index (R=0.695; p=0.01).The cytokines'evaluation in relation to outcomes revealed that NR-SLE-patients who achieved remission had baseline higher level of IL-2 than active patients (p=0.01). LN-patients with higher levels of IL-6 during the follow-up were less likely to reach remission(p=0.02) as well as those with higher levels of IL-17 (p=0.01). Higher baseline levels of IL-17 were observed in patients who developed persistent proteinuria than those who didn't (p=0.02).

Conclusion Higher disease-activity index appears as predictor of worse renal outcome. Higher IL-6 and IL-17 levels emerge as possible biomarkers of more aggressive LN. IL-2 seems to have a protective role in NR-SLE.

P100 EFFICACY OF ANIFROLUMAB IN MULTI-REFRACTORY SKIN MANIFESTATIONS OF SYSTEMIC LUPUS ERYTHEMATOSUS: CASE SERIES

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Objective To evaluate the efficacy of anifrolumab (ANI) in refractory cutaneous manifestations of systemic lupus erythematosus (SLE) in real-world settings.

Methods Patients with SLE, according to ACR 1997 criteria and/or SLICC 2012 criteria, and refractory cutaneous manifestations who received anifrolumab were included. Demographic and clinical characteristics and laboratory values were documented at baseline and last visit of follow-up. Prior use of immunosuppressives and glucocorticoids, as well as adverse events were also recorded. SLE disease activity was measured with Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) and Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI).

Results Eighteen patients (94%female, mean age 44.3 ±12.6years, mean disease duration 13.7±7.6years) received ANI. In all patients, active skin involvement was the main reason for ANI initiation. Mean (SD) SLEDAI at baseline was 7.1 (2.6) and mean prednisone dose was 6 (4.9) mg/day. Additionally, 8 and 4 patients had low levels of C3/C4, and positive anti-dsDNA. Mean (SD) CLASI (Actvity/Damage) at ANI baseline was 12/3.4 (2.9/4.6). Skin rash had previously proven refractory to a mean (SD) 4.5 (1.9) prior immunosuppressive agents (excluding hydroxychloroquine and glucocorticoids). Fifteen patients had not responded to belimumab, seven to cyclophosphamide, and four each to rituximab, thalidomide. We observed an impressive and rapid response of active skin lesions very early following ANI initiation, even after the first infusion. After a mean (SD) 7.1 (5.8) months of follow-up, fifteen patients are still receiving ANI without loss of efficacy and mean (SD) daily prednisone dose is 3.4 (3.5).