**Conclusions** Although less prominent compared to HSCT, proteasome inhibition with Bortezomib promoted a therapeutically relevant PC depletion in refractory SLE. Nevertheless, for sustained responses, PC depletion needs to be combined with therapeutic strategies targeting their precursor B cells, e.g. with rituximab, as indicated by our preclinical studies in murine lupus.

## S2a – Prediction & prevention

### S2A:4 VALIDATION OF REMISSION AND LUPUS LOW DISEASE ACTIVITY STATE AS PREDICTORS OF ORGAN DAMAGE IN SLE

[1]M Petri, [1]D Goldman, [2]L Magder. *[1]Johns Hopkins University School of Medicine, Baltimore, MD, USA; [2]University of Maryland, Baltimore, MD, USA*

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**Background/purpose** Outcome measures that combine control of SLE activity and prednisone reduction are clinically relevant. A clinical goal in SLE is to reduce risk of long-term organ damage. We assessed whether two recently proposed disease activity outcomes were predictive of future damage.

**Methods** For each month of follow-up in a large SLE cohort, we determined whether the patient was in Clinical Remission (as defined by the DORIS working group) or lupus low disease activity state (LLDAS) (as defined by Franklyn *et al.*). Clinical Remission was defined as a PGA<0.5, clinical SLEDAI=0 and no prednisone or immunosuppressants. Clinical Remission on Treatment allowed for prednisone ≤5 mg/day and immunosuppressant use. LLDAS was defined as a SLEDAI ≤4, PGA≤1.0, no major organ activity, and no new activity. LLDAS on treatment allowed for prednisone use ≤7.5 mg/d and immunosuppressants. Damage was defined using the SLICC/ACR Damage index.

**Results** There were 81 118 person-months observed among 2026 patients (92% female, 53% Caucasian, 39% African-American). Table 1 shows the rates of damage, per person month, in subgroups defined by Remission or LLDAS.

Damage rates were relatively low when LLDAS was achieved at least 50% of the time. These rates were similar to those experienced by patients who met a more stringent treatment restriction with Remission on Treatment at least 50% of the time.

**Conclusion** Percent time in LLDAS had a clear dose response for rate ratios of organ damage. The equivalence of LLDAS and DORIS remission on treatment is welcome news, as LLDAS on treatment >50% of the time is an easier goal to achieve (3 times more person-months observed in our cohort) and more realistic as a clinical trial outcome.

**Abstract S2A:4 Table 1** Rates of new damage, in subgroups defined by past levels of disease activity

| Percentage of Prior Months in: | Number of person-months observed | Number of months with an increase in SLICC/ACR Damage Index | Rate of damage per 100 person months | Rate Ratios | P-values |
|---|---|---|---|---|---|
| Clinical Remission | - | - | - | - | - |
| None | 35,772 | 406 | 1.13 | 1.0 (Ref) | - |
| Not none, but < 25% | 14,358 | 102 | 0.71 | 0.60 (0.48,0.75) | <0.0001 |
| 25% to 50% | 6573 | 50 | 0.76 | 0.66 (0.46,0.94) | 0.023 |
| 50% to 75% | 3845 | 27 | 0.70 | 0.63 (0.42,0.97) | 0.035 |
| 75%+ | 1,641 | 10 | 0.61 | 0.58 (0.30,1.15) | 0.12 |
| Clinical Remission on Treatment | - | - | - | - | - |
| | - | - | - | - | - |
| None | 16,491 | 250 | 1.52 | 1.0 (Ref) | - |
| Not none, but < 25% | 20,169 | 170 | 0.84 | 0.54 (0.44,0.67) | <0.0001 |
| 25% to 50% | 14,344 | 103 | 0.72 | 0.46 (0.36,0.60) | <0.0001 |
| 50% to 75% | 8396 | 54 | 0.64 | 0.43 (0.30,0.60) | <0.0001 |
| 75%+ | 2,789 | 18 | 0.65 | 0.45 (0.27,0.75) | 0.0019 |
| LLDAS | - | - | - | - | - |
| None | 30,366 | 343 | 1.13 | 1.0 (Ref) | - |
| Not none, but < 25% | 10,880 | 106 | 0.97 | 0.86 (0.69,1.07) | 0.18 |
| 25% to 50% | 5012 | 40 | 0.80 | 0.70 (0.51,0.98) | 0.037 |
| 50% to 75% | 8494 | 60 | 0.71 | 0.63 (0.48,0.83) | 0.0010 |
| 75%+ | 7,527 | 46 | 0.61 | 0.54 (0.40,0.73) | <0.0001 |
| LLDAS on Treatment | - | - | - | - | - |
| None | 7,656 | 117 | 1.53 | 1.0 (Ref) | - |
| Not none, but < 25% | 10,555 | 134 | 1.27 | 0.83 (0.65,1.06) | 0.14 |
| 25% to 50% | 12,686 | 129 | 1.02 | 0.66 (0.51,0.85) | 0.0013 |
| 50% to 75% | 18,151 | 133 | 0.73 | 0.48 (0.37,0.61) | 0.0010 |
| 75%+ | 13,141 | 82 | 0.62 | 0.40 (0.30,0.54) | <0.0001 |