

increased DNA binding. Baseline HSS score  $6.5 \pm 2.5$ , PGA score  $1.28 \pm 0.54$ , and CLASI activity score  $8.7 \pm 9.7$ . 16 (42.1%) of the patients were Ro [SS-A] positive, and 15 (35.7%) were positive for antiphospholipid antibodies [aPL], which included lupus anticoagulant [LA], anticardiolipin [aCL] and anti-phosphatidylserine [aPS] antibodies.

CC-220 as a Cereblon E3 ubiquitin ligase modulator binds to cereblon and facilitates Ikaros and Aiolos degradation. CC-220 inhibits plasmablast differentiation and reduces Ikaros (IKZF1) and Aiolos (IKZF3) protein levels in B-cells, T-cells, and monocytes.

Efficacy and safety outcomes as well as biomarker parameters are pending.

**Conclusions** CC-220 is a compound that modulates the Cereblon E3 ubiquitin ligase, resulting in reduction in Ikaros and Aiolos protein levels in B cells, T cells, and monocytes. The efficacy and safety of CC-220 in the treatment of SLE is currently being evaluated in a Phase 2 study.

**Acknowledgements** Abstract is being presented on behalf of the CC-220 study team.

**Trial Registration** NCT02185040

## Clinical Epidemiology and Outcomes Research

### CE-01 REMISSION IN SYSTEMIC LUPUS ERYTHEMATOSUS – DURABLE REMISSION IS RARE

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**Background** Remission is the ultimate goal in SLE. In this study, we applied four definitions of remission agreed on by an international collaboration (DORIS) to a large clinical cohort.

**Materials and methods** We applied the DORIS definitions of Clinical Remission, Complete Remission (requiring negative serologies), Clinical Remission on Treatment (ROT) and Complete ROT. 2307 patients entered the cohort from 1987 to 2014. Patients not in remission at cohort entry were followed prospectively. We used the Kaplan-Meier approach. Cox regression was used to identify baseline factors associated with time to remission.

**Results** The median time to remission was 8.7, 11.0, 1.8 and 3.1 years for Clinical Remission, Complete Remission, Clinical ROT

and Complete ROT, respectively. High baseline treatment was the major predictor of a longer time to remission, followed by high baseline activity. The median duration of remission for all definitions was just three months. Based on Kaplan-Meier estimates, we determined the durability of remission by specified times as shown in Table 1. African-American ethnicity, baseline low C3 and baseline hematologic activity were associated with longer time to remission for all definitions. Baseline anti-dsDNA and baseline low C4 were associated with longer time to Complete Remission and Complete ROT. Baseline low C4 was also a negative predictor for Clinical Remission.

**Conclusions** These findings demonstrate that it was easier to reach ROT than remission. Baseline treatment and baseline disease activity were strongly associated with the time to remission for all definitions. We found that the durability of remission was very short, regardless of definition. African-American ethnicity, baseline low C3 and baseline hematologic activity were associated with a longer time to remission. Baseline anti-dsDNA and baseline low C4 were negative predictors for complete remission and for complete ROT. Our results provide further insights into the frequency and durability of remission in SLE and call attention to the major role of baseline activity and baseline treatment in predicting remission.

### CE-02 PEER APPROACHES TO LUPUS SELF-MANAGEMENT (PALS): A NOVEL LUPUS PEER MENTORSHIP INTERVENTION

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**Background** Systemic Lupus Erythematosus (SLE) is a chronic autoimmune disease that is associated with increased morbidity, mortality, health care costs and decreased quality of life. While evidence-based self-management interventions that incorporate both social support and health education have reduced pain, improved function, and delayed disability among lupus patients, African Americans and women are still disproportionately impacted by lupus. In the United States, African Americans have three to four times greater prevalence of lupus, risk of developing lupus at an earlier age, and lupus-related disease activity, damage, and mortality compared with Caucasians, with the highest rates experienced by African American women. Persistent disparities may be due to the non-responsiveness of existing programs to the unique needs of African Americans and/or women with lupus. Peer mentoring interventions are effective in other chronic conditions that disproportionately affect minorities, such as diabetes, HIV, and kidney disease, but there is currently no empirically tested peer mentoring intervention developed for SLE patients.

**Materials and methods** A literature review, needs assessment, and interviews with patients guided the development of a peer mentor training manual and a peer mentoring intervention. African American women with lupus are being recruited from the SLE database at the Medical University of South Carolina. Seven mentors will be trained and paired with 21 mentees to provide modelling and reinforcement to participants by telephone for at least 60 minutes every week for 12 weeks. The goal of mentorship will be to encourage mentees to engage in activities that promote the learning of disease self-management skills and to support the mentees' practice of these learned skills during the

**Abstract CE-01 Table 1** Durability of remission in% by specified times

Duration	Clinical remission	Complete Remission	Clinical remission on treatment	Complete remission on treatment
120 days	43.8	41.0	44.5	4.03
240 days	24.3	21.3	22.7	18.6
1 year	13.2	12.1	13.4	9.3
2 years	5.6	5.2	5.6	3.6
5 years	1.2	2.0	0.6	0.7
10 years	0.4	1.3	0.3	0.7

three-month intervention period. Mentee outcomes of health-related quality of life, self-management (including treatment adherence), and disease progression (including disease activity, damage, and cytokine balance) will be obtained at baseline, mid-intervention (6 weeks from baseline), and immediately post-intervention (12 weeks from baseline), using validated tools. Descriptive statistics and effect sizes will be calculated to determine clinically important (>0.3) changes.

**Results** This study is currently in progress. Preliminary results will be shared.

**Conclusions** Given the success of the peer mentoring approach in other chronic conditions that disproportionately impact minorities, and its responsiveness to the needs of this unique population, this intervention could result in health improvements that have not been attainable with other interventions. This could lead to significant reductions in disparities and have considerable public health impact.

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#### CE-03 ORGAN-SPECIFIC SYSTEMIC LUPUS ERYTHEMATOSUS ACTIVITY DURING PREGNANCY IS ASSOCIATED WITH ADVERSE PREGNANCY OUTCOMES

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**Background** Previous studies have found a relationship between overall systemic lupus erythematosus (SLE) activity and adverse pregnancy outcomes. We sought to investigate whether 5 types of specific types of SLE activity either in the 6 months prior to conception or during pregnancy were related to adverse pregnancy outcome.

**Materials and methods** 149 pregnancies occurred in 114 women with mean age 23.7 (SD 6.8) years at SLE diagnosis and 31.0 (SD 5.3) at conception. 68% were White, 15% Hispanic, 11% Black, 7% Asian. Seven women had a history of antiphospholipid syndrome and 23 had a prior adverse pregnancy outcome. During the study period, 40 (27%) pregnancies had an adverse outcome. Cytopenias (15%) and nephritis (11%) were the most common types of SLE activity during pregnancy. In univariable analyses, nephritis 6 months before conception (OR 7.3, 95% CI: [1.5, 35.2]) and during pregnancy OR 4.4 (1.3–14.9) and cytopenias during pregnancy (OR 4.8 [1.7, 14.0]) were significantly associated with adverse outcome. Hispanic ethnicity, prior adverse pregnancy outcome, and steroid and/or azathioprine use during pregnancy were also associated with adverse outcome. In multivariable analyses, nephritis (OR 3.5 [1.0–12.2]), cytopenias (OR 4.2 [1.4,12.2]) and serositis (OR 5.7 [1.1–30.3]) during pregnancy were associated with adverse outcome (Table 1)

**Results** 149 pregnancies occurred in 114 women with mean age 23.7 (SD 6.8) years at SLE diagnosis and 31.0 (SD 5.3) at conception. 68% were White, 15% Hispanic, 11% Black, 7% Asian. Seven women had a history of antiphospholipid syndrome and 23 had a prior adverse pregnancy outcome. During the study period, 40 (27%) pregnancies had an adverse outcome.

#### Abstract CE-03 Table 1 Odds ratios for adverse pregnancy outcome (n = 40) among 149 pregnancies

Predictor	Number of occurrences	Univariable OR (95% CI):	Model 1 <sup>#</sup> OR (95% CI):	Model 2 <sup>#</sup> OR (95% CI):
<b>Organ-specific activity six months prior to conception</b>				
Cytopenia	17	2.6 (0.8–8.5)	1.8 (0.5–6.0)	1.6 (0.5–5.4)
Nephritis	10	7.3 (1.5–35.2)	4.6 (0.9–23.4)	3.3 (0.6–17.9)
Skin disease	15	1.0 (0.3–3.9)	1.3 (0.4–5.0)	1.2 (0.3–4.8)
Arthritis	13	0.8 (0.2–3.6)	0.7 (0.1–3.2)	0.7 (0.1–3.0)
Serositis	5	1.8 (0.2–14.1)	1.6 (0.2–12.7)	1.0 (0.1–7.8)
<b>Organ-specific activity during pregnancy</b>				
Cytopenia	23	4.8 (1.7–13.9)	4.2 (1.4–12.2)	3.9 (1.3–11.4)
Nephritis	16	4.4 (1.3–14.9)	3.5 (1.0–12.2)**	3.6 (1.0–12.8) <sup>5</sup>
Skin disease	13	1.9 (0.5–7.1)	1.3 (0.3–5.4)	1.3 (0.3–5.2)
Arthritis	8	3.2 (0.6–16.2)	3.7 (0.8–18.5)	3.9 (0.8–19.7)
Serositis	8	4.8 (0.9–25.5)	5.7 (1.1–30.3)	5.9 (1.0–34.0)**

Adverse pregnancy outcome: pre-eclampsia, preterm <37 weeks, miscarriage (fetal loss at 12–20 weeks gestation), stillbirth (fetal loss at ≥20 weeks gestation), SLE-related elective termination OR and 95% CI: from generalised linear mixed models to account for correlated data among 114 women carrying a total of 149 pregnancies

<sup>#</sup>Model 1: adjusted for ethnicity (Hispanic/non-Hispanic) and prior adverse pregnancy outcome

<sup>#</sup>Model 2: model 1 + corticosteroid and/or azathioprine use six months before conception, and hydroxychloroquine use six months before conception

\*\*p = 0.046 <sup>5</sup>p = 0.045 <sup>+</sup>p = 0.049

Cytopenias (15%) and nephritis (11%) were the most common types of SLE activity during pregnancy. In univariable analyses, nephritis 6 months before conception (OR 7.3, 95% CI: [1.5, 35.2]) and during pregnancy OR 4.4 (1.3–14.9) and cytopenias during pregnancy (OR 4.8 [1.7, 14.0]) were significantly associated with adverse outcome. Hispanic ethnicity, prior adverse pregnancy outcome, and steroid and/or azathioprine use during pregnancy were also associated with adverse outcome. In multivariable analyses, nephritis (OR 3.5 [1.0–12.2]), cytopenias (OR 4.2 [1.4,12.2]) and serositis (OR 5.7 [1.1–30.3]) during pregnancy were associated with adverse outcome (Table 1).

**Conclusions** The majority of pregnancy outcomes were favourable in this SLE cohort. After adjusting for ethnicity, prior adverse pregnancy outcomes, and medications during pregnancy, nephritis, cytopenias and serositis disorders during pregnancy were associated with an elevated risk of adverse pregnancy outcome. Prior studies have suggested variable impact of lupus nephritis on pregnancy outcomes, but this study uniquely demonstrates an additional association between cytopenias and serositis during pregnancy and adverse pregnancy outcomes.

#### CE-04 SEX DIFFERENCES IN HEALTHCARE UTILISATION, END-STAGE RENAL DISEASE AND MORTALITY AMONG U.S. MEDICAID BENEFICIARIES WITH INCIDENT LUPUS NEPHRITIS

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