

America and included 147 patients from the placebo plus SOC arms of two randomised Phase II/III trials in moderately-to-severely active lupus patients without acute nephritis. BILAG-based response was evaluated at weeks 12, 24, 36, 48, and 52. Both cross-sectional and longitudinal analyses of response rates were performed. Baseline clinical variables that discriminated persistent responders and non-responders were identified using logistic regression.

Results Cross-sectional response rates for patients treated with placebo plus SOC decreased from 46% to 37% between 12–52 weeks (Figure 1). The rate of complete and sustained response, i. e., response at all visits between 12–52 weeks, was only 14.3% (95% CI: 8.6%–19.9%). Agreement between response status at 12 weeks and 36–52 weeks was low ($\kappa = 0.15$ – 0.25); furthermore only 31% of initial 12 week responders maintained response at all subsequent visits. Baseline factors contributing to persistent response to SOC included fewer active organ systems, high C3 levels, and type of background therapy.

Conclusions An endpoint based on a sustained rather than landmark response may reduce high placebo response rates in SLE trials that continue aggressive SOC. Further exploration to assess the power of this endpoint to improve discrimination between active and placebo arms is indicated. The observed lack of stability in response to SOC over time highlights a potential weakness with shorter studies that use an endpoint of improvement. Our data also confirm earlier reports that the likelihood of response in the placebo group depends on the severity of disease and the aggressiveness of background treatments.

Acknowledgements Lupus Foundation of America Collective Data Analysis Initiative Group.

CT-06 FACTORS AFFECTING THE ATTITUDES OF PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS REGARDING POTENTIAL CLINICAL TRIAL PARTICIPATION

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10.1136/lupus-2016-000179.78

Background Systemic Lupus Erythematosus (SLE) is an autoimmune disorder affecting skin, joints, kidneys, brain and other organs. Clinical trial recruitment is especially challenging in this patient population. To address challenges of recruiting patients with SLE into clinical trials, we conducted a survey study to: (1) explore patients' satisfaction with their current treatment; (2) assess participants' motivations to switch to a new treatment; and (3) identify the characteristics of patients willing to participate in a clinical trial.

Materials and methods 259 members of an online patient network with SLE aged 18–77 (mean age = 47; 96% female, 78% white) completed an online survey about their experience and attitudes. Data was collected over 7 days. The Chi square test was used to analyse the distribution of categorical variables; two sample t-tests to compare group means, and Pearson r correlation to identify the associations between continuous variables.

Results 60% of SLE patients reported being at least "somewhat satisfied" with their current treatment; 74% name worsening symptoms as an important factor for changing medications. Those patients (36%) who were motivated to change to a new treatment reported a slightly more severe daily impact of SLE (mean = 3.6 on a scale 1: not at all – 5 very much) than patients who did not view new treatment availability as a reason to

change their current medication (SLE impact mean = 3.3; $t(258) = 2.49$; $p < 0.01$). 29% say knowing that a trial drug has never been tested before will increase the likelihood of their participation in the trial. Correlation analyses revealed slight, but significant association between a favourable view of novel drug trials and higher number of treatments, frequency of healthcare utilisation, and lupus daily impact (r ranged 0.13 – 0.22, $p < 0.03$). Disease-related factors positively associated with interest in clinical trial participation are SLE daily impact ($r = 0.26$, $p < 0.03$), headaches ($\chi^2 = 14.06$, $p < 0.01$), and pain ($\chi^2 = 8.8$, $p < 0.05$); treatment-related factors are burden of treatment, frequency of flares, frequency of healthcare utilisation, number of medications (r ranged 0.14 – 0.18, $p < 0.03$), and use of pain medications ($\chi^2 = 12.6$, $p < 0.05$).

Conclusions Investigators may achieve a higher recruitment rate by targeting: 1) patients whose SLE symptoms are under poor control and who therefore frequently utilise the healthcare system; and 2) those patients who are experiencing more pain and headaches and more frequently using pain medications.

CT-07 A PHASE 2, RANDOMISED, PLACEBO-CONTROLLED, DOUBLE-BLIND, ASCENDING DOSE STUDY TO EVALUATE EFFICACY, SAFETY, AND TOLERABILITY, PHARMACOKINETICS, PHARMACODYNAMICS AND PHARMACOGENETICS OF CC-220 IN SUBJECTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS

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10.1136/lupus-2016-000179.79

Background To evaluate the efficacy, safety and tolerability of CC-220 in subjects with Systemic Lupus Erythematosus [SLE] in a Phase 2, randomised, double-blind, placebo-controlled, ascending dose study

Materials and methods 42 adult SLE subjects with serological and clinical activity for ≥ 6 months, and a baseline Hybrid SELENA-SLEDAI [HSS] score ≥ 4 were randomised to one of four escalating doses of CC-220 or matching placebo. The four active treatments included CC-220 0.3 mg QOD, 0.3 mg QD, 0.3 mg alternating with 0.6 mg QD, and 0.6 mg QD, randomised 4:1 active to placebo in each group, for 12 weeks of treatment followed by 12 weeks of observational follow-up, and/or optional long term extension. Stable doses of corticosteroids (≤ 10 mg prednisone or equivalent daily), non-steroidal anti-inflammatory drugs, and antimalarials were permitted.

Efficacy assessments included HSS, Cutaneous Lupus Area and Severity Index [CLASI] skin scores, Physician Global Assessment [PGA], swollen joint counts [SJC] and tender joint counts [TJC].

Biomarkers, such as expression of Aiolos and Ikaros, and change from baseline in lupus serology markers and cell subsets were also assessed.

Safety assessments included type, frequency, severity, and relationship of adverse events [AEs] to CC-220, laboratory (chemistry, haematology including B cell differentiation and immunoglobulin profiling, inflammatory markers, urinalysis), electrocardiogram [ECG], physical examination and overall tolerability.

Results Baseline subject demographics included 39 women (93%) with a mean age 47.2 ± 10.6 years, and included 64% White, 31% Black, 2% Asian and 2% other races. The mean duration of SLE was 10.3 ± 8.0 years, 88% had arthritis, 78% cutaneous disease, 55% alopecia, 25% mucosal ulcers, and 19%

increased DNA binding. Baseline HSS score 6.5 ± 2.5 , PGA score 1.28 ± 0.54 , and CLASI activity score 8.7 ± 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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10.1136/lupus-2016-000179.80

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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10.1136/lupus-2016-000179.81

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