are positive for anti-ds DNA, anti-Sm, and/or anti-nuclear antibodies. Exclusion criteria include: active, clinically significant, interstitial lung disease/pulmonary arterial hypertension; proteinuria >4 g/day and/or eGFR <45 mL/min/1.73 m²; recent acutely worsened renal function; and use of oral corticosteroids >30 mg/day prednisone equivalent, injectable corticosteroids, or change in dose of corticosteroids within 2 weeks prior to or during screening. The primary efficacy endpoint family comprises response based on SLE Responder Index (SRI)-4 among all patients and SRI-6 in patients with high disease activity (baseline SLEDAI-2K ≥10) at Week 52. Success on either endpoint will support a conclusion of efficacy. Primary safety endpoints include nature, severity, and incidence of adverse events (AEs) and serious AEs. Secondary endpoints include the time to first severe flare up to Week 52, SRI-4 and SRI-6 response at Week 52 in the serologically active subgroup, and disease activity over time, including attaining low disease activity, and change from baseline in Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI)-A at each study visit. The primary analysis is planned when all patients have completed the safety follow up for the 52-week blinded portion of the study, entered the OLE, or have discontinued prematurely from the study.

Results Recruitment is ongoing. Target enrolment is 432 to 468 participants. The first patient was randomized on 20 January 2017; study completion is expected end of 2019.

Conclusions This study will provide clinical proof of concept of the efficacy and safety of evobrutinib in SLE.

Funding Source(s): Merck KGaA, Darmstadt, Germany

Abstract 213 Figure 1 Study design

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Methods Data derive from the baseline visit of the California Lupus Epidemiology Study (CLUES), an ongoing cohort of patients in the San Francisco Bay Area with confirmed SLE diagnoses, drawn from a variety of clinical sources and prior SLE studies. Participants provided access to medical records and had a visit with a study physician in which clinical labs were drawn. Disease damage was measured using the SLICC/ACR Damage Index (SDI), calculated at the study visit. Age of diagnosis was ascertained by the study physician or from the medical records. Race/ethnicity (White, African American, Hispanic of any race, and Asian) and educational attainment (high school or less, some college, college graduate) were determined by patient report. Due to the small sample size, patients from other racial groups were excluded from this analysis (n=5). Using multiple linear regression, we estimated a model of SDI as a function of race/ethnicity and age of diagnosis, plus terms for interaction between the variables. The model controlled for sex, current age, and education.

Background Earlier age of SLE onset is associated with greater disease damage, even after taking into account the effects of current age and disease duration. We sought to determine if this association was consistent across racial and ethnic groups, given the differences in disease severity among these groups.

Results Recruitment is ongoing. Target enrolment is 432 to 468 participants. The first patient was randomized on 20 January 2017; study completion is expected end of 2019.

Conclusions This study will provide clinical proof of concept of the efficacy and safety of evobrutinib in SLE.

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Abstract 213 Figure 1 SDI by race/ethnicity and age of diagnosis
Relationship Between Serum Level of Renalase and Lupus Nephritis Activity

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Background (LN)Lupus nephritis is a major risk for overall morbidity and mortality in SLE (Systemic lupus erythematosus), and despite potent anti-inflammatory and immunosuppressive therapies still ends in Chronic Kidney Disease (CKD) or End Stage Renal Disease (ESRD) for too many patients. Renalase is a novel, kidney secreted cytokine-like protein that promotes cell survival.

Aim of the work studying the relationship between level of Human Serum Renalase (RNLS) with LN and its role in the disease activity and progression.

Methods For the current cross-sectional study 23 healthy controls and 48 patients with LN were screened and 30 subjects were selected. These patients were subdivided into two equal groups according to disease activity measured by SLEDAI (SLE Disease Activity Index). Human Serum Renalase (RNLS) concentration was measured by a highly sensitive, commercial sandwich enzyme immunoassay which uses (RNLS) antibody concentration was negative and close to zero (0.00027 ms/ng/mL; p=0.86; figure 1). The predicted QTcF effect at geometric mean Cmax for the highest dose (1512 ng/mL) was 1.16 ms, with an upper limit of 3.26 ms for the 90% two-