

analysis, the following were all associated with serious infection ( $p < 0.01$ ): splenectomy, use of cyclophosphamide, mycophenolate and rituximab, which is shown in figure 1 and figure 2.

**Conclusions** In the largest observational European Registry of SLE patients, one third of the jSLE patients suffered serious infections. Higher SLEDAI score, renal involvement and immunosuppressant and corticosteroids use were independent associated factors to the presence of serious infection in jSLE, as well as smoking.

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182

### IMMUNOMODULATORY MEDICATION USE FOR YOUTH WITH NEWLY-DIAGNOSED SYSTEMIC LUPUS ERYTHEMATOSUS

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**Background** To examine immunomodulatory medication use for youth with systemic lupus erythematosus (SLE) during their first year of care.

**Methods** We conducted a retrospective cohort study using de-identified administrative claims for 2000 to 2013 from Optum® Clinformatics® DataMart for youth ages 10–24 years with an incident diagnosis of SLE (3 International Classification of Diseases, Ninth Revision codes for SLE 710.0, each >30 days apart). We determined the proportion of subjects filling a prescription for an immunomodulatory medication, defined as hydroxychloroquine or an immunosuppressant (excluding glucocorticoids), within 3, 6, and 12 months after the first SLE diagnosis code (index date). We used a Cox proportional hazards regression model to examine associations between time to immunomodulatory prescription fill within 12 months and demographic and disease factors (age, race/ethnicity, household education level, region, history of seizures/stroke, history nephritis).

**Results** We identified 650 youth with an incident diagnosis of SLE. In the 12 months following the index date, 511 (79%) of youth had a prescription fill for an immunomodulatory medication. For those with a prescription fill for hydroxychloroquine in the first year ( $n=457$ , 70%), 374 (58%) and 407 (63%) of youth filled the medication within 3 months and 6 months from the index date, respectively (table). For those with a prescription fill for an immunosuppressant ( $n=221$ , 34%) in the first year, 114 (18%) and 162 (25%) of youth filled the medication within 3 months and 6 months from the index date, respectively (Table). Location in the Northeast region was significantly associated with a longer time to immunomodulatory prescription fill within 12 months, compared to location in the South (HR=0.686, 95% CI 0.50–0.94). There were no statistically significant associations for the other demographic and disease factors.

**Conclusions** Among youth with newly-diagnosed SLE, hydroxychloroquine use is prevalent although not universal, and immunosuppressant use is notably low during the first year of care. As poorly controlled SLE disease activity can lead to organ damage, further work is needed to identify potential

### Abstract 182 Table 1 Immunomodulatory Medication Use in Youth with Newly-Diagnosed SLE, N=650

Proportion with prescription fills after first SLE diagnosis code, n (%)	Within 3 months	Within 6 months	Within 1 year
Immunomodulatory medication (hydroxychloroquine or immunosuppressant)	428 (66)	460 (71)	511 (78)
Hydroxychloroquine	374 (58)	407 (63)	457 (70)
Immunosuppressant	114 (18)	162 (25)	221 (34)

Immunosuppressant medications include: mycophenolate mofetil, azathioprine, leflunomide, methotrexate, tacrolimus, and oral cyclophosphamide.

factors contributing to suboptimal immunomodulatory medication use in this population.

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183

### A PHASE 1B/2A TRIAL OF TOFACITINIB, AN ORAL JANUS KINASE INHIBITOR, IN SYSTEMIC LUPUS ERYTHEMATOSUS

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**Background** A pharmacologic intervention that modulates JAK/STAT signaling pathways represents a novel approach for the treatment of Systemic Lupus Erythematosus (SLE). In animal models of SLE, tofacitinib improved clinical features, immune dysregulation and vascular dysfunction. The STAT4 risk allele is associated with higher risk of severe manifestations in SLE. We hypothesized that immune modulation in response to JAK/STAT inhibition would be more robust in SLE subjects that carry the STAT4 risk allele.

**Methods** We conducted a phase 1b/2a randomized, double-blind, placebo-controlled clinical trial of oral tofacitinib, 5 mg twice daily, in 30 SLE subjects (2:1 drug to placebo ratio) with mild to moderate disease activity, stratified by the presence or absence of STAT4 risk allele. Study duration was 84 days (56 days of active treatment ; 28 days of off drug). In addition to recording adverse events (AEs), lipoprotein profile, non-invasive vascular function studies, immuno-phenotyping, and gene expression studies were performed.