clinically meaningful (Figure 1), tapering of CS therapy to reduce placebo responses, and ongoing review by a panel of lupus trial experts to ensure accuracy and consistency of patient data.

Conclusions Afimetoran is a novel, oral, potent, selective inhibitor of TLR 7/8. Using insights from past lupus clinical trial designs, a phase 2b clinical trial design was optimized to test whether inhibition of TLR7/8 is beneficial for the treatment of SLE. This study is currently enrolling patients globally (EudraCT 2019–004021-25; NCT04895696).

PO.6.133 DYNAMICAL TRAJECTORY OF GLUCOCORTICOID TAPERING AND DISCONTINUATION IN REAL-WORLD PATIENTS WITH NEWLY DIAGNOSED SYSTEMIC LUPUS ERYTHEMATOSUS: THE GULP STUDY

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Purpose Glucocorticoids (GCs) are recommended in patients with systemic lupus erythematosus (SLE), in combination with hydroxychloroquine (HCQ) or immunosuppressant, but should be tapered or discontinued in the medium to long-term to minimize detrimental effects. A sub-analysis of the multicenter Early Lupus inception cohort was performed to investigate the real-world trajectory of Glucocorticoids (GCs) Use in newly diagnosed SLE Patients (the GULP study) and the associated outcomes.

Methods The GULP study enrolled patients starting prednisone (PDN) ≥5mg/day and concomitant HCQ or immunosuppressant within 12 months of SLE classification. SLE core set variables were recorded at baseline and then every six months for 2 years, including changes in PDN dose, ECLAM and BILAG active domains. The SLICC/ACR Damage Index (SDI) and a 0–10 global health visual analog scale (GH-VAS) were also recorded. Regression models analyzed the damage accrual and GH-VAS in different GCs tapering and discontinuation trajectories.

Results Overall, 127 SLE patients with a mean age of 36.7 (± 13.4) years and a median disease duration of 6.1 (1.3 - 11.5) months were included. At baseline 98 (77.2%) patients received HCQ, 81 (63.8%) received conventional immunosuppressants, and 57 (44.9%) received a combination of them. The median daily dose of PDN at baseline was 12.5 (6.3–25.0) mg/day and significantly decreased to 5.4 (4.3–9.4) mg/day at 12-month and 4.9 (2.5–6.6) mg/day at 24-month (p<0.001). At the end of follow-up, 73 (57.5%) successfully tapered PDN doses below 5 mg/day, and 17 (13.4%) discontinued GCs within a 2-year follow-up (Figure 1). Overall, 99 (78%) patients tapered the PDN dose below 5 mg/day: 34 (26.8%) within 6 months, 35 (27.6%) within 12 months, 22 (17.3%) within 18 months and 8 (6.3%) within 24 months of follow-up; 42.4% of patients who tapered PDN and 46.4% of those who never tapered PDN below 5mg/day required to increase the PDN dose within the end of the 2-year follow-up. A higher daily dose of PDN resulted in a greater probability (OR 1.4 per mg/day; 95%CI 1.3–1.5; p<0.001) of GCs tapering regardless of disease activity, whereas ECLAM (OR 1.6; 95%CI 1.2–2.3; p=0.004) and BILAG (OR 1.9; 95%CI 1.3–3.0; p=0.004) were independently associated with the risk of increasing GCs dose. In patients taking PDN <5mg/day,

Abstract PO.6.133 Figure 1 Heatmap of the mean daily prednisone dose interval during the 24 months follow-up since diagnosis