treatment data were collected according to a standardised protocol. jSLE patients (≤18 years old) were selected from this cohort and matched for gender and disease duration in a 1:1 ratio with aSLE patients. Data from the enrolment visit (V0) and last visit (VL) were analysed in this study.

Results There were 148 jSLE patients with sufficient information for analysis who were matched with 148 aSLE patients. Fever and lymphadenopathy ($p<0.001$) and hypocomplementemia ($p=0.002$ at V0) were significantly more common in jSLE, while cardiovascular manifestations were significantly more common in aSLE patients ($p=0.008$ at VL). Disease activity measured by the SLE Disease Activity Index (SLEDAI) was higher in the jSLE group at V0 (median SLEDAI 4 vs 2, $p=0.05$) and at VL (median SLEDAI 2.5 vs 0, $p=0.007$). A significantly higher proportion of jSLE patients received immunosuppressants (intravenous cyclophosphamide, mycophenolate mofetil, azathioprine and ciclosporin) ($p=0.003$ at V0, $p<0.001$ at VL) and intravenous methylprednisolone ($p<0.001$ at V0 and VL) compared to aSLE patients.

Conclusions A higher proportion of jSLE patients have fever, lymphadenopathy, hypocomplementemia; more active disease requiring greater use of immunosuppressants compared to aSLE patients. Early diagnosis and treatment of jSLE may prevent development of major organ involvement, in particular renal and neuropsychiatric disease.

11. SLE pregnancy and reproductive health

LP-200 RELAPSING POLYCHONDRITIS AND SYSTEMIC LUPUS ERYTHEMATOSUS OVERLAP IN A 26 YEAR OLD G2P1 PREGNANT MOTHER WITH SUCCESSFUL PREGNANCY OUTCOME

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Description We report a case of a 26 year old female, Gravida 2 Para 1 (G2P1) 30 weeks age of gestation (AOG), with shortness of breath and chest discomfort. History revealed 4 years prior, patient has been experiencing chronic urticaria in the face, abdomen and extremities aggravated by sunlight. Upon consult, she was given Prednisone 20mg twice daily and Chlorphenamine 4mg daily but was lost to follow up. Four years later, she was hospitalized due to joint pains, butterfly rashes and shortness of breath. Using the SLICC criteria (cutaneous, serositis, synovitis, FANA), patient was managed as SLE. Antiphospolipid and cardiolipin panels were negative. She was started on Hydroxychloroquine 200mg twice daily, Prednisone 20mg daily and Mycophenolate 1gram daily. However, discontinued her medications upon pregnancy. Few months later, she was readmitted for chest discomfort, shortness of breath and uterine contractions. She has red raised patched rashes on extremities, periorbital edema, saddle nose, and cauliflower ears. Hence, Relapsing Polychondritis on top of SLE, G2P1 30 weeks AOG on preterm labor was entertained. 2D echocardiogram revealed normal left ventricular size with normal systolic/diastolic function, ejection fraction of 64%, dilated left atrium with trivial pericardial effusion o 0.5cm. She was started on Dexamethasone 6mg every 12 hours for 4 doses, Nifedipine 10mg thrice daily, Hydroxycholoroquine 200mg daily, Enoxaparin 40mg every 12 hours and Colchine 0.5mg daily. Symptoms improved and preterm labor was controlled. She was discharged with the following medications: Hydroxychloroquine 200mg daily, Prednisone 20mg daily, Azathrioprine 50mg daily, and Aspirin 80mgdaily. After a few weeks, she successfully delivered a live term baby boy with no complications.

Conclusions Systemic Lupus Erythematosus with Relapsing Polychondritis overlap during pregnancy carry a high maternal and fetal risk. Thus, a multidisciplinary approach with close medical, obstetric, and neonatal monitoring is necessary to optimize both maternal and fetal outcome.

12. SLE treatment

LP-179 DESIGN OF 2 PHASE 3, DOUBLE-BLIND, PLACEBO-CONTROLLED, GLOBAL TRIALS OF DEUCRAVACITINIB, AN ORAL, SELECTIVE, ALLOSTERIC TYROSINE KINASE 2 (TYK2) INHIBITOR, IN PATIENTS WITH ACTIVE SYSTEMIC LUPUS ERYTHEMATOSUS

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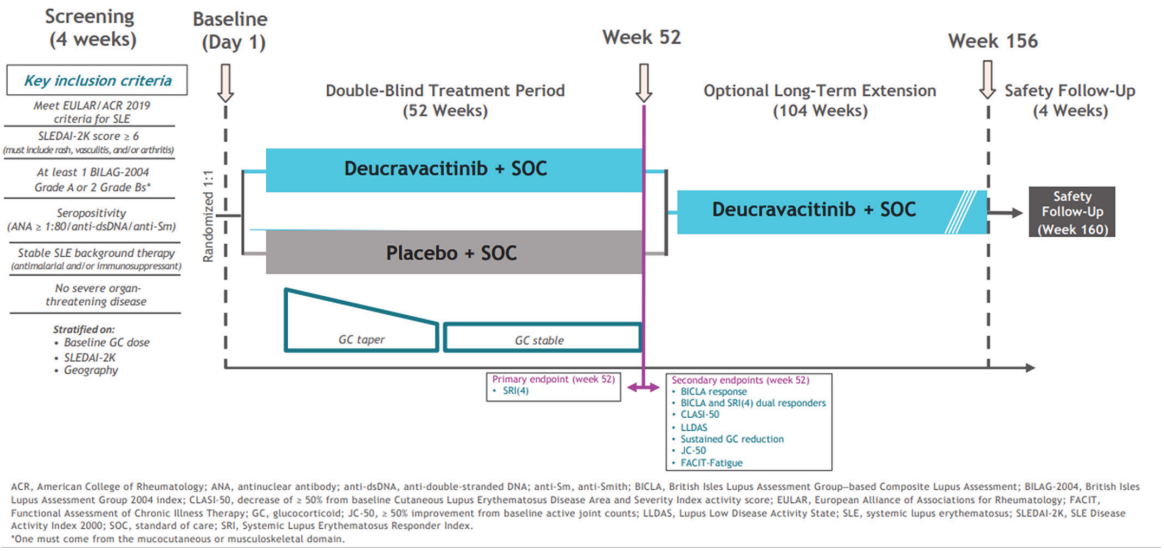
Background Deucravacitinib is a first-in-class, oral, selective, allosteric tyrosine kinase 2 (TYK2) inhibitor, approved in multiple countries for the treatment of adults with plaque psoriasis.[1] [2] Deucravacitinib demonstrated efficacy across the primary endpoint and all key secondary endpoints in a phase 2 trial in patients with systemic lupus erythematosus (SLE).[3] Here, we describe 2 phase 3 trials currently underway to assess the efficacy and safety of deucravacitinib in patients with active SLE. These phase 3 trials have been designed to replicate the successful elements of the phase 2 trial, including its glucocorticoid-tapering strategy and rigorous management structure.[3]

Methods In these phase 3, randomized, double-blind, placebo-controlled, global trials (POETYK SLE-1 [NCT05617677], POETYK SLE-2 [NCT05620407]), adults (aged 18–75) with active SLE on background standard-of-care treatment will be randomized (1:1) to placebo or deucravacitinib for 52 weeks of double-blind treatment (figure 1). Patients on glucocorticoids will be instructed to taper, unless significant disease activity is present, to a threshold dose level during the double-blind treatment period. At week 52, patients may choose to continue in a 104-week open-label extension phase, in which all patients receive deucravacitinib. Key eligibility criteria and study design are depicted below (figure 1) rimary endpoint of SLE Responder Index (SRI[4]) and all secondary endpoints will be assessed at week 52 (table 1) safety and tolerability will be assessed throughout the trial

Results Planned randomization in each trial includes 490 patients (245 per treatment group) in 27 countries across North and South America, Europe, and Asia-Pacific.



Abstract LP-179 Figure 1 POETYK SLE-1 and POETYK SLE-2 Trial Design

Abstract LP-179 Table 1 Primary and Secondary Endpoints Assessed at Week 52

Table. Primary and Secondary Endpoints Assessed at Week 52

Primary Endpoint
• Proportion of patients who achieve an SLE Responder Index (SRI[4]) response
Secondary Endpoints
• Proportion of patients who achieve a British Isles Lupus Assessment Group-based Composite Lupus Assessment (BICLA) response
• Proportion of patients with simultaneous achievement of SRI(4) and BICLA response (dual responders)
• Proportion of patients who achieve a ≥ 50% reduction in Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI-50) among patients with CLASI activity score ≥ 10 at baseline
• Proportion of patients who achieve Lupus Low Disease Activity State (LLDAS)
• Proportion of patients maintaining ≤ 7.5 mg/day glucocorticoid dose from weeks 24 to 52
• Proportion of patients who achieve a ≥ 50% reduction in active joints (Joint-Count 50) among patients with ≥ 6 active joints at baseline
• Change from baseline in Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue score

Conclusions The phase 3 POETYK SLE trials will further evaluate the efficacy and safety of deucravacitinib, an oral, selective, TYK2 inhibitor, in patients with active SLE.

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LP-180 DESIGN OF A PHASE 2, DOUBLE-BLIND, PLACEBO-CONTROLLED, GLOBAL TRIAL OF DEUCRAVACITINIB, AN ORAL, SELECTIVE, ALLOSTERIC TYROSINE KINASE 2 (TYK2) INHIBITOR, IN PATIENTS WITH ACTIVE DISCOID AND/OR SUBACUTE CUTANEOUS LUPUS ERYTHEMATOSUS

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10.1136/lupus-2023-KCR.255

Background Deucravacitinib is a first-in-class, oral, selective, allosteric TYK2 inhibitor approved in multiple countries for the treatment of adults with plaque psoriasis.[1–2] Deucravacitinib demonstrated efficacy across multiple outcome measures, including achievement of ≥50% reduction in Cutaneous Lupus Erythematosus Disease Area and Severity Index-Activity score (CLASI-50), in a phase 2 trial in patients with systemic lupus erythematosus (SLE)[3] and is being investigated in two phase 3 trials (NCT05617677; NCT05620407). Patients with discoid and/or subacute cutaneous lupus erythematosus (DLE/SCLE) have elevated expression of Type I interferons (IFN).[4] Deucravacitinib mediates signaling of Type I IFN, IL-12, and IL-23 and may be an effective treatment for patients with DLE/SCLE.[5] Results of this ongoing phase 2 trial (NCT04857034) will characterize the efficacy and safety of deucravacitinib compared with placebo in patients with active DLE/SCLE with or without SLE.

Methods This phase 2, global, randomized, double-blind, placebo-controlled trial is enrolling adults (aged 18–75) with biopsy-confirmed clinical diagnosis of DLE/SCLE. Key eligibility criteria and study design are depicted below (figure 1). Eligible patients will be randomized (1:1:1) to treatment with placebo or deucravacitinib (dose 1 or 2) for 16 weeks. At week 16, all patients randomized to placebo will be rerandomized (1:1) to treatment with deucravacitinib dose 1